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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDPOINTE HEALTHCARE INC.,)

Plaintiff,)

vs.)

APOTEX INC. and APOTEX CORP.,)

Defendants.)

Civil Action No. 06-164

REDACTED - PUBLIC VERSION

**PLAINTIFF'S ANSWERING BRIEF IN OPPOSITION TO
APOTEX'S MOTION TO ADD NEW ARGUMENTS
TO APOTEX'S CLAIM CONSTRUCTION PAPERS**

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Dated: March 14, 2008

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INTRODUCTION

Plaintiff MedPointe Healthcare, Inc., now known as Meda Pharmaceuticals Inc. ("Meda"), respectfully submits this opposition to Apotex's motion to add new arguments to its previously filed claim construction papers ("Apotex's Motion to Supplement").

As the first part of its motion, Apotex seeks to amend and supplement its Response to MedPointe's Opening Brief on Claim Construction Issues ("Apotex's Response Brief") (D.I. 113) with cites and excerpts from the official transcript of the Hague deposition of the inventor of the patent-in-suit, Dr. Helmut Hettche. Apotex admits that it mischaracterized a portion of Dr. Hettche's testimony in its Response Brief and seeks to file a revised brief, in part to correct this error. Meda agrees that the record should be supplemented to correct this error, but believes that the other Apotex mischaracterizations of Dr. Hettche's testimony should also be corrected.

As the second part of its motion, Apotex seeks to supplement its Response Brief to add new arguments. Apotex bases its motion on the premise that Meda raised a "new" argument for the first time in MedPointe's Response Brief on Claim Construction Issues ("Meda's Response Brief") (D.I. 112). But this is a false premise. The argument in question — that the spray of Claim 9 could not include an eye product as Apotex's expert admitted — was fully set out in MedPointe's Opening Brief on Claim Construction Issues ("Meda's Opening Brief") (D.I. 103). In fact, Meda quoted the same portion of testimony from Apotex's expert, Dr. Schwartz, in support of its argument in both its Opening and Response Briefs. Apotex thus had ample notice of this argument from Meda's Opening Brief and a full and fair opportunity to respond. Apotex seeks a second bite at the apple. But this request is wholly unjustified and should be denied.

NATURE AND STAGE OF THE PROCEEDINGS

In accordance with the Court's June 5, 2007 Amended Rule 16 Scheduling Order (D.I. 85), the parties submitted their simultaneous opening briefs on claim construction issues on December 17, 2007 (D.I. 102, 105) and their simultaneous response briefs on claim January 9, 2008 (D.I. 112, 113).

Some six weeks later, on February 22, 2008, Apotex requested that Meda agree to Apotex's request to file a supplemental claim construction brief containing: (1) portions of the official transcript of Dr. Hettche's Hague deposition, in part to correct an erroneous reference to this testimony in its response brief; and (2) new argument that "eye sprays" somehow existed in the prior art despite the fact that Apotex's expert testified to the exact opposite. (*See Ex. A.*)

Meda responded that it would agree to the first aspect of the request, correcting references to Dr. Hettche's Hague deposition testimony, if given a chance to review Apotex's proposed supplementation and if given a chance to respond to any uncorrected testimony that remained. (*See Ex. B.*) Meda, however, made clear that it would not agree to the introduction of Apotex's new "eye spray" argument, because the evidence and argument it was designed to respond to had been fully set out in Meda's Opening Brief. (*See id.*) Apotex had had a full and fair opportunity to respond in its Response Brief but failed to do so. Additionally, Meda noted that Apotex's proposed supplementation was directly contrary to the deposition testimony of its own expert, Dr. Schwartz. (*See id.*)

Apotex declined to permit Meda to review its proposed motion to supplement (*see Ex. C*) and, on February 26, 2008, filed its Motion To Supplement Apotex's Response Brief On Claim Construction ("Apotex's Motion to Supplement") (D.I. 121, 122).

SUMMARY OF THE ARGUMENT

Meda agrees that supplementation with the official transcript of Dr. Hettche's Hague deposition is warranted to correct mischaracterizations of his testimony in Apotex's Response Brief on claim construction. Meda, however, believes that any such supplementation should correct *all* of Apotex's mischaracterizations of Dr. Hettche's testimony, not merely the one to which Apotex now admits.

Apotex concedes that it grossly overstated the magnitude of a side effect experienced by Dr. Hettche following his first ocular administration of an azelastine hydrochloride solution.

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(See Ex. D, Hettche Dep. Tr. at 15.) The record should be supplemented with the official transcript of Dr. Hettche's Hague deposition to correct this mischaracterization.

Unfortunately, Apotex's Response Brief mischaracterizes other portions of Dr. Hettche's testimony relating to the type of solution Dr. Hettche administered to his eye.

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record should be supplemented with the official transcript to correct all of these mischaracterizations. For the convenience of the Court, attached as Exhibit E is a chart comparing Apotex's mischaracterizations with the official record of Dr. Hettche's testimony. For Apotex's requested supplementation on this issue to be complete, Meda respectfully submits that these mischaracterizations should be corrected as well.

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Meda opposes Apotex's inappropriate effort to add new arguments to its Response Brief. Apotex argues that Meda raised a "new" argument in its Response Brief. But this is false. The argument in question was set forth in Meda's opening and response papers and Apotex had a full and fair opportunity to respond on the schedule set by the Court. This aspect of Apotex's motion is a transparent and highly improper effort to get a second chance to rebut arguments made of record on December 17, 2007 in Meda's Opening Brief. Meda's argument regarding the non-existence of eye sprays did not change between its Opening and Response Briefs. Apotex has no justification to add new arguments now, six weeks after claim construction briefing has closed and less than two months from trial. In any event, Apotex's proposed new argument is contrary to its own expert's testimony and futile.

Meda respectfully submits that the record should be supplemented with Dr. Hettche's official Hague deposition transcript to correct all of Apotex's mischaracterizations in its Response Brief. The remaining portion of Apotex's Motion to Supplement should be denied.

ARGUMENT

I. THE RECORD SHOULD BE SUPPLEMENTED WITH DR. HETTICHE'S OFFICIAL HAGUE DEPOSITION TRANSCRIPT TO CORRECT ALL OF APOTEX'S MISCHARACTERIZATIONS.

Meda agrees that the record should be supplemented with the official Hague deposition transcript to correct Apotex's mischaracterizations of Dr. Hettiche's testimony. Unlike Apotex, however, Meda believes that any such supplementation should correct *all* of Apotex's mischaracterizations, not merely the one to which Apotex now admits.

Apotex admits in its Motion to Supplement that, contrary to the account in its Response brief,

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The record should be supplemented with the

¹ Apotex's motion to supplement also blatantly mischaracterizes Meda's document production and wrongly accuses Meda of having "assured the Court" it had produced documents that, according to Apotex, were in fact not produced. (See Apotex's Supp. Mem. at 2, n. 1.) These statements are false.

Meda has brought two separate infringement actions against Apotex, the present action and *MedPointe Healthcare Inc. v. Apotex Inc. and Apotex Corp.*, C.A. No. 07-204-SLR (D. Del.). The present action accuses Apotex of infringing the '194 patent through its filing of ANDA 77-954, seeking to manufacture an azelastine hydrochloride nasal spray. The C.A. No. 07-204-SLR action accuses Apotex of infringing the '194 patent through its filing of ANDA 78-621, seeking to manufacture an azelastine hydrochloride ophthalmic solution. Although Meda sought to consolidate these actions, Apotex opposed that effort, and this Court declined to order consolidation. (See 5/3/2007 Hearing Tr. at 4-11.) (D.I. 77)

At the May 3, 2007 hearing with the Court, Apotex challenged the scope of Meda's document production in the nasal spray case. The documents that Apotex represented to the Court that it was seeking, and that the Court ordered Meda to produce, were documents relating to early research on nasal and non-nasal azelastine formulations, including testing on animal models. (See 5/3/2007 Hearing Tr. at 27) However, counsel for Apotex repeatedly

official transcript of Dr. Hettche's Hague deposition as Apotex requests to correct this mischaracterization.

Apotex's Response Brief, however, also mischaracterizes other portions of Dr. Hettche's testimony relating to the type of azelastine hydrochloride solutions that Dr. Hettche first administered to his nose and eyes.

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represented to the Court that they were not seeking "eye drop documents," and, in particular, were not seeking documents relating to application of azelastine hydrochloride to the eyes of human subjects. Counsel for Apotex explicitly stated: "*they are not eye drop documents that we're talking about, Judge*" (*id.* at 23 (emphasis added)) and ". . . we are *not* trying to get documents relating to applying Astelin in the eye per se." (*Id.* at 27 (emphasis added).)

Meda supplemented its production accordingly in May and June, 2007, per this Court's order. Meda properly did not produce eye drop or Optivar[®] related documents (including documents relating to Dr. Hettche's self-administration of azelastine directly to the eye) other than in the eye drop case. And it produced these documents in the eyedrop case in a timely fashion. *MedPointe Healthcare Inc. v. Apotex Inc. and Apotex Corp.*, Civil Action No. 07-204-SLR (D. Del.) (D.I. 19) ("Document production shall be completed on or before January 17, 2008.").

Apotex's accusations are baseless and explicitly contradicted by Apotex's own representations to the Court in this case. Apotex should withdraw these accusations.

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This distinction between a "formulation" and a "solution" is important. Additional ingredients present in nasal and ophthalmic formulations are typically used to maintain a pH and isotonicity similar to that of nasal and eye fluids, respectively. The purpose of adjusting a solution's pH and/or isotonicity prior to use in the nose or eyes is to reduce patient discomfort. (See Ex. G, Introduction to Pharmaceutical Dosage Forms 325, 338 (1985).)

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Claim 4 of the '194 patent claims

"A method as set forth in claim 1 in which the *medicament* contains 0.003 to 0.5% (weight/weight) of azelastine. . . ." (Ex. H at Claim 4 (emphasis added).) The patent is clear that the invention is a "medicament for nasal use or for use in the eye which contains as active

ingredient azelastine or a physiologically acceptable salt." (Ex. H at Abstract.) Although the patent limits the active ingredient to azelastine, it fully anticipates that other inactive excipients will be added to make "a medicament." Both parties agree that "a medicament" can include excipients.

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² Dr. Hettche's deposition testimony also provides the necessary context in which to read Exhibit G (OPTI 615-650) to Apotex's Response Brief (attached hereto as Ex. I).

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testing azelastine solutions with concentrations of 0.05%, 0.1%, and 0.2 %, Apotex's interpretation must fail.

Instead, the ambiguous nature of these statements most likely arose during translation from German to English. The report Apotex cites, and the other two reports in which the statement appears, are all translations into English of original German reports. When these reports are compared with reports that were originally written in English, the correct interpretation is apparent.

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The reports do not indicate that these concentrations are the maximum concentrations that are safe and effective for human use.

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Thus, contrary to Apotex's unfounded assertions, these documents provide no evidence that a 0.5% solution was unsafe or

II. CONTRARY TO APOTEX'S MISCHARACTERIZATIONS OF DR. HETTICHE'S HAGUE DEPOSITION, HIS TESTIMONY WAS FULLY CONSISTENT WITH MEDA'S PROPOSED CLAIM CONSTRUCTION.

Meda proposes that the claim term "physiologically acceptable" entails physiological safety, efficacy and tolerability and that the claim term "a medicament" means a product that includes a medicinal substance that has acceptable safety, efficacy, and tolerability for use in humans. (Meda's Opening Brief at 13-15.) Contrary to Apotex's assertion, the entire dosage range of the medicament in Claim 4 is enabled under Meda's proposed construction. In other words, medicaments containing 0.003-0.5% azelastine can be safe, effective and tolerable when applied directly to nasal tissues or the conjunctival sac of the eye.

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intolerable and are fully consistent with Dr. Hettiche's testimony and with Meda's proposed claim constructions.

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For example, many FDA-approved nasal preparations are known to cause similar discomfort when first administered. (*See, e.g.*, Ex. M, Physicians' Desk Reference 928 (1987) (noting that "[s]ome patients may experience transient nasal stinging" with Nasalcrom[®] Nasal Solution and that "[p]atients may experience a transient stinging or burning sensation following application of OPTICROM[®] Ophthalmic Solution").)

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III. APOTEX INAPPROPRIATELY SEEKS TO ADD NEW ARGUMENTS IN RESPONSE TO AN ARGUMENT FULLY SET OUT IN MEDA'S OPENING CLAIM CONSTRUCTION BRIEF.

Contrary to Apotex's rhetoric, the allegedly "new" argument in Meda's Response Brief was also set forth in Meda's Opening Brief. As Meda argued in its Opening Brief, and again in its Response Brief, extrinsic evidence supports Meda's proposed claim construction that the term "applied by spraying" excludes application to the eye. In particular, the testimony of Apotex's own expert, Dr. Schwartz, demonstrates that persons of ordinary skill in the art at the relevant time would interpret the term "applied by spraying" to exclude ocular administration because they would not have been aware of any eye sprays and would not believe that the '194 patent

disclosed and claimed the world's first eye spray. Apotex seeks to distort Meda's argument to justify its inappropriate attempt to add new arguments to its papers. But Meda's papers speak for themselves and Apotex has indisputably been aware of Meda's argument since Meda filed its Opening Brief on December 17, 2007.

The Federal Circuit has rejected similar attempts by a party to supplement its briefing papers when the arguments the supplemental papers seek to address were "squarely raised" by the opposing party before the party's original briefing papers were submitted to the court. *See, e.g., Sun Coast Merchandise Corp. v CCL Products Enterprises, Inc.*, 179 Fed. Appx. 6, 2006 WL 1044244 (Fed. Cir. Apr. 21, 2006) (upholding the district court's refusal to permit a party opposing a summary judgment motion to supplement the record on an issue that was "squarely raised" by the moving party in its opening summary judgment brief) (attached as Ex. N).

As Meda explained in its Opening Brief, "[e]xtrinsic evidence confirms that the claim term 'applied by spraying' excludes application to the eyes. Apotex's medical expert witness, Dr. Schwartz, admitted that 'eye sprays' do not exist and therefore the use of the term 'spray' would indicate to a person of ordinary skill in the art that that particular dosage form could not be applied to eyes." (Meda's Opening Brief at 26.) In support of this argument, Meda quoted the following excerpt of the testimony of Apotex expert Dr. Schwartz in its Opening Brief:

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(Ex. O, Schwartz Dep. Tr. at 114:17-115:12 (emphases added).)

In its Response Brief, Meda reiterated this argument, stating that the "language [in the specification], however, does not provide that 'spray' in the '194 patent somehow includes the world's first eye spray.

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(See Meda's Response Brief at 23-24.) Once again, to support this argument, Meda quoted *precisely* the same excerpt of Dr. Schwartz's testimony quoted in Meda's Opening Brief.

Meda's argument, as set forth in both its Opening and Response Briefs and as admitted by Apotex's own expert, is that persons of ordinary skill in the art would not have been aware of any eye sprays. (See Meda's Opening Brief at 26

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Meda's Response Brief at 24

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) Consequently, as Meda argued in both of its claim construction briefs, the person of ordinary skill in the art would not have interpreted the term "applied by spraying" to include ocular administration. (See Meda's

Opening Brief at 26 ("therefore the use of the term 'spray' would indicate to a person of ordinary skill in the art that that particular dosage form could not be applied to eyes.").)

In attempting to justify its inappropriate request to add new arguments to its papers, Apotex mischaracterizes Meda's Response Brief as arguing that "the spraying application of claim 9 must be limited to nose spray applications because eye spray applications are entirely unknown in history." (Apotex 's Motion to Supplement at 1.) But Meda makes no such argument. Indeed, Apotex's Response Brief reveals that Apotex was fully aware of Meda's actual argument:

There is also nothing in the term 'applied by spraying' which excludes from the scope of language application to the eyes. *Now it could be that in fact, as a practical matter, no one every [sic] applies by spraying to the eyes, but if so then that is a factual question.* It is not a matter of claim construction, and there is no reason for the court to try to answer that as a question of law.

(Apotex's Response Brief at 18.)

In its already-filed Response Brief, Apotex correctly articulated and timely responded to Meda's argument that neither Apotex's own expert nor the person of ordinary skill in the art would believe that "applied by spraying" included an "eye spray" because, "as a practical matter, no one every [sic] applies by spraying to the eyes." When it filed its Response Brief two months ago, Apotex argued that that was a question of fact. Now, Apotex apparently has changed its position and seeks to submit new arguments to respond to Meda's argument as a question of law. But Apotex has already had a full and fair opportunity to respond to this argument in accordance with the Court's claim construction briefing schedule, and in fact has *already provided a response*. Apotex should not be permitted to add new arguments to its papers simply because it decided to flip-flop on the issue.

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IV. APOTEX'S PROPOSED NEW ARGUMENTS ARE FUTILE AND CONTRARY TO ITS OWN EXPERT'S TESTIMONY.

Apotex's motion to supplement should also be denied because Apotex's proposed new arguments are irrelevant to claim construction and futile. Apotex's new arguments attempt to rely on additional extrinsic evidence that Apotex apparently believes contradicts the testimony of *Apotex's own expert*.

As a preliminary matter, the Federal Circuit has established that extrinsic evidence cannot be used to contradict the intrinsic evidence. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322 (Fed. Cir. 2005). As the Federal Circuit stated in *Phillips*, "while extrinsic evidence can shed useful light on the relevant art, we have explained that it is less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (internal quotations omitted). The court emphasized the paramount importance of intrinsic evidence in claim construction, stating that the "claims themselves provide substantial guidance as to the meaning of particular claim terms," and the "specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Id.* at 1314-15 (internal citations and quotations omitted).

The intrinsic evidence in this case unambiguously supports Meda's construction of the phrase "applied by spraying" to exclude application to the eyes. The only "spray" the specification teaches is a nasal spray. (See Ex. H at col. 2, ll. 17 ("... form of a spray (preferably a nasal spray)"), col. 2, ll. 23 ("Through the use of nasal drops or a nasal spray. . ."), col. 6, l. 7 ("Nasal spray or nasal drops or eye drops . . ."), col. 7, ll. 19-20 (for a "dosage aerosol," "a conventional applicator . . . permits introduction of the active substance into the nose of the patient.")) The specification further distinguishes between a nasal spray and any eye

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product. (*See id*) There is no hint in the specification that "applied by spraying" could encompass an eye spray.

Under *Phillips*, Meda's reliance on the testimony of Apotex's expert as confirmation of the intrinsic evidence is entirely appropriate. *Phillips*, 415 F.3d at 1318 ("extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes"). Dr. Schwartz's testimony demonstrates that, from the point of view of the person of ordinary skill, the phrase "applied by spraying" would not be interpreted to encompass an eye spray.

In light of Dr. Schwartz's testimony and the *Phillips* decision, the extrinsic evidence that Apotex cites in its motion is puzzling. Apotex cites only two patents that issued before the effective filing date of the '194 application, which is the relevant time for purposes of claim construction.³ One patent issued in 1967 and the other patent issued in 1970. Apotex cites these two patents for the proposition that, allegedly, "eye sprays have been known in the art for decades." (*See* Apotex's Supp. Mem. at 4.) These two patents, however, do not represent the type of extrinsic evidence preferred by the *Phillips* court for use in claim construction, which included "dictionaries" and "learned treatises." *Phillips*, 415 F.3d at 1317-18 ("Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention.") These two patents simply do

³ *See Phillips*, 415 F.3d at 1313 ("[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.") Apotex also cites a patent that issued December 1996, nearly eight years after the effective filing date of the '194 patent application, and an article from 2005, nearly 17 years after the effective filing date of the '194 patent application. These have no relevance to claim construction. *See id*.

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not speak to the meaning of the term "spray" to the person of ordinary skill in the art as of November 1988, the effective filing date of the patent application.

Moreover, the patents cited by Apotex actually support Meda's arguments that the term "spray" does not encompass dosage forms to be applied to the eyes. (See Ex. P, U.S. Pat. No. 3,314,426 (April 18, 1967) at col. 1, ll. 26-28) ("The most common device for applying a medicament to the human eye is an eyecup formed of glass, plastic, metal or the like."); Ex. Q, U.S. Pat. No. 3,506,001 (April 14, 1970) at col. 1, ll. 27-36 ("The conventional methods of administering medicated solutions to the eye are by the use of droppers and eye cups or baths. . . . [with the] use of a fine spray . . . considerable difficulty is experienced . . . in accurately directing the medication into the eye."); Ex. R, U.S. Pat. No. 5,588,564 (December 31, 1996) at col. 1, ll. 12-13 ("[e]ye treatment solutions are normally self-administered by using either an eye cup or a dropper."))

Apotex's proposed new argument in support of its strained claim construction, like its original arguments, ignores both the intrinsic evidence and the extrinsic evidence provided by its own expert. Perhaps having realized that these arguments are insufficient, Apotex wishes to shore them up. But this is no basis for allowing Apotex to add new arguments weeks after the close of the Court's claim construction briefing schedule. This conclusion is confirmed by the fact that Apotex's proposed new argument and evidence are futile, given that they are impermissible under *Phillips* and irrelevant to the question of how a person of ordinary skill in the art at the relevant time would have understood the phrase "applied by spraying." Accordingly, Apotex's motion to supplement this aspect of its claim construction papers should be denied.

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CONCLUSION

For the foregoing reasons, Meda respectfully requests that the record be supplemented with the official transcript of Dr. Hettche's Hague deposition to correct all of Apotex's mischaracterizations of this testimony and that the remainder of Apotex's Motion to Supplement be denied.

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Dated: March 14, 2008

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 14, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF and caused the same to be served on the plaintiff at the address and in the manner indicated below:


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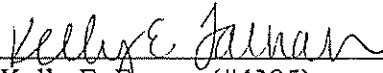
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EXHIBIT A

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Subject MedPointe Healthcare, Inc. v. Apotex, Inc. et al
(Astelin)

Dear Anne,

Pursuant to our earlier conversation, we are requesting MedPointe's agreement to Apotex's filing a supplement to Apotex's Response Brief on Claim Construction ("Apotex's Response Brief").

On page 9 of Apotex's Response Brief, we referred to testimony obtained from Dr. Hettche in Germany. Because the official text of that testimony was unavailable, we requested leave of the Court to supplement. Apotex has now obtained a certified translation of the official text, and seeks MedPointe's agreement to supplement the record with official Hague Convention Testimony. As I indicated in our conversation, Apotex will also correct the record as it relates to the duration of the burning sensation experienced by Dr. Hettche after administering azelastine directly to the eyes.

Also, in MedPointe's Response Brief on Claim Construction Issues ("MedPointe's Response Brief"), MedPointe argued for the first time that eye sprays were unknown in history. Previously, MedPointe had argued claim 9 was limited to a nasal spray based on the '194 patent specification and prosecution history. MedPointe's experts also relied on the specification and prosecution history in their reports to argue for a limitation of claim 9 to a nasal spray. At no time did MedPointe argue claim 9 must be limited to nasal sprays because eye sprays have been **unknown in history** (quite different and a leap of logic from Dr. Schwartz's testimony that he was not aware of an eye spray for allergies being commercially marketed). Therefore, Apotex is inquiring whether MedPointe would object to Apotex's supplementing the record with evidence that eye sprays are not only known in history, but were known for decades before November 1987? I'm sure MedPointe would agree that it is in the best interest of the parties for the Court to be properly apprised of the state of the art relating to delivery options for eye medicaments as of 1987. Perhaps MedPointe was unaware of the existence of eye sprays at the time of filing MedPointe's Response Brief and would like to correct its mistake at this time?

Please let me know if you will agree to Apotex's proposed supplementation. In the event MedPointe does not agree, Apotex will note MedPointe's objections in its memorandum in support of supplementation.

Sincerely,

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02/22/2008 03:20 PM

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cc "Morse, Hartwell" <hpmorse@welshkatz.com>, "White,
James" <jpwhite@welshkatz.com>, "Krol, Michael"
<makrol@welshkatz.com>, "Segrest, Philip"
bcc
Subject Re: MedPointe Healthcare, Inc. v. Apotex, Inc. et al (Astelin)

Dear Steve,

We would like to review Apotex's supplemental brief regarding the official Hague Deposition testimony before it is filed - before we agree to supplementation on that issue. Also, MedPointe's agreement would be conditioned on Apotex's agreeing to MedPointe's filing a supplemental brief in response, if MedPointe believes a response is warranted.

MedPointe does not agree to any supplementation regarding Apotex's eye spray argument. It is MedPointe's position that the argument Apotex refers to in MedPointe's response brief is the same as an argument MedPointe made in its opening brief (see MedPointe opening brief at 26-27). In fact, MedPointe quoted exactly the same excerpt of Dr. Schwartz's testimony in both briefs. Apotex therefore was fully on notice of this argument from MedPointe's opening brief and had a full and fair opportunity to respond in its responsive brief. Apotex's apparent recent decision that its response was insufficient does not justify any supplemental filing. I note in addition that you have mischaracterized Dr. Schwartz's testimony - contrary to your description, Dr. Schwartz stated that there is no such thing as an eye spray for allergies and that he had never heard of such an eye spray (see, e.g., Schwartz Dep. Tr. at 114:17-115:12: "Q. And would you agree with me that there is no such thing as an eye spray for allergies? A. No. No eye spray. . . ."). Your statement that he testified "that he was not aware of an eye spray for allergies being commercially marketed" is simply incorrect.

Regards,

Anne

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EXHIBIT C

"Benson, Stephen"
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02/22/2008 04:50 PM

To "Anne Toker" <AToker@kirkland.com>
cc "Morse, Hartwell" <hpmorse@welshkatz.com>, "White, James" <jpwhite@welshkatz.com>, "Krol, Michael" <makrol@welshkatz.com>, "Segrest, Philip" <pdsegrest@welshkatz.com>, "Breisblatt, Robert" <rbbreisblatt@welshkatz.com>, "Horwitz, Richard L." <rhhorwitz@Potteranderson.com>
Subject RE: MedPointe Healthcare, Inc. v. Apotex, Inc. et al (Astelin)

Dear Anne,

Given your objection to Apotex's supplementation regarding MedPointe's late argument that "the '194 patent somehow includes the world's first eye spray", we do not see the utility in having MedPointe review Apotex's supplemental memorandum

Apotex intends to file its motion to supplement early next week. We will note MedPointe's objection in the memorandum supplementing Apotex's motion. Furthermore, Apotex will not object to MedPointe's filing a response if it deems such a response is warranted.

Sincerely,

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EXHIBIT D

EXHIBIT D
REDACTED
IN ITS ENTIRETY

EXHIBIT E

EXHIBIT E
REDACTED
IN ITS ENTIRETY

EXHIBIT F

EXHIBIT F
REDACTED
IN ITS ENTIRETY

EXHIBIT G

Introduction to Pharmaceutical Dosage Forms

HOWARD C. ANSEL, Ph.D.
*Professor and Dean, College of Pharmacy
The University of Georgia*

FOURTH EDITION



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1985

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1000 g of water solution isosmotic

prepare a solution when using electric the calculation is isosmotic pressure of particles, substance effect that dissociation; the alter the quantity notic pressure. If de in weak solution, then each 100 or 1.8 times as by 100 molecules association factor. letter *i*, must be en we seek to de-smotic solution of eight, 58.5):

$$\frac{2}{3}x = 9.09 \text{ g}$$

chloride in 1000 g on isosmotic with icated previously, : solution is taken :y) with the body

then, may be calculated:

r 1000 g of water

been determined might be named, generally) used:

ances 1 0

into 2 1.8

into 3 2.6

into 4 3.4

into 5 4.2

Since 0.9% sodium chloride solution is considered to be isosmotic (and isotonic) with lacrimal fluid, other medicinal substances are compared with regard to their "sodium chloride equivalency." An often used rule states:²

*quantities of two substances that are tonic equivalents are proportional to the molecular weights of each multiplied by the *i* value of the other.*

Using the drug atropine sulfate as an example:

Molecular weight of sodium chloride = 58.5;

i = 1.8

Molecular weight of atropine sulfate = 695;

i = 2.6

$$\frac{695 \times 1.8}{58.5 \times 2.6} = \frac{1 \text{ (g)}}{x \text{ (g)}}$$

x = 0.12 g of sodium chloride represented by 1 g of atropine sulfate

Thus, the sodium chloride equivalent for atropine sulfate is 0.12 g. To put it one way, 1.0 g of atropine sulfate equals the "tonic effect" of 0.12 g of sodium chloride. To put it another way, atropine sulfate is 12% as effective as an equal weight of sodium chloride in contributing toward tonicity. When a combination of drugs is used in a prescription or formulation to be rendered isotonic, each agent's contribution to tonicity must be taken into consideration. For instance, consider the following prescription:

Atropine Sulfate	1%
Sodium Chloride	q.s. to isotonicity
Sterile Purified Water, ad	30.0 mL

To make the 30 mL isotonic with sodium chloride, $30 \text{ mL} \times 0.9\% = 0.27 \text{ g}$ or 270 mg of sodium chloride would be required. However, since 300 mg of atropine sulfate is to be present, its contribution to tonicity needs to be taken into consideration. Since the sodium chloride equivalent for atropine sulfate is 0.12, its contribution is calculated as follows:

$$0.12 \times 300 \text{ mg} = 36 \text{ mg}$$

Thus, $270 \text{ mg} - 36 \text{ mg} = 234 \text{ mg}$ of sodium chloride would actually be required

Table 12-1 presents an abbreviated list of sodium chloride equivalents. A more complete list may be found in pharmaceutical calculations or physical pharmacy textbooks.

As a convenience, the USP presents precalculated amounts of some common ophthalmic drugs which may be used to prepare isotonic solutions. Some of the drugs and the related values are presented in Table 12-2. The data shown are utilized in the following manner. One gram of each of the drugs listed, when added to purified water, will prepare the corresponding volume of an isotonic solution. For instance, 1 g of atropine sulfate will prepare 14.3 mL of isotonic solution. This solution may then be diluted with an isotonic vehicle to maintain the isotonicity while changing the strength of the active constituent in the solution to any desired level. For instance, if a 1% isotonic solution of atropine sulfate is desired, the 14.3 mL of isotonic solution containing 1 g of atropine sulfate would be diluted to 100 mL (1 g atropine sulfate in 100 mL = a 1% w/v solution) with an isotonic vehicle. By utilizing sterile drug, sterile purified water, a sterile isotonic vehicle, and aseptic techniques, a sterile product may be prepared. In addition to being sterile and isotonic, the diluting vehicles generally used are also buffered and contain suitable preservative to maintain the stability and sterility of the product.

Buffering

Buffers may be used in an ophthalmic solution for one or all of the following reasons: (1) to reduce discomfort to the patient, (2) to ensure drug stability, and (3) to control the therapeutic activity of the drug substance.

Normal tears, having a pH of about 7.4, possess some buffer capacity. The introduction of a medicated solution into the eye stimulates the flow of tears, which attempts to neutralize any excess hydrogen or hydroxyl ions introduced with the solution. Most drugs used ophthalmically, such as alkaloidal salts, are weakly acidic and have only weak buffer capacity. Normally, the buffering action of the tears is capable of neutralizing the ophthalmic solution and is thereby able to prevent marked discomfort. However, a few drugs—notably pilocarpine hydrochloride and epinephrine bitartrate—are quite acid and overtax the buffer capacity of the lacrimal fluid. For maximum comfort, an ophthalmic solution should have the same pH

amphenicol, colistin sulfate, neomycin, polymyxin B sulfate, and nystatin, the latter agent used to combat fungal infections. These agents are generally formulated into ear drops (solutions or suspensions) in a vehicle of anhydrous glycerin or propylene glycol. These viscous vehicles permit maximum contact time between the medication and the tissues of the ear. In addition, their hygroscopicity causes them to draw moisture from the tissues thereby reducing inflammation and diminishing the moisture available for the life process of the microorganisms present. To assist in relieving the pain which frequently accompanies ear infections, a number of anti-infective otic preparations also contain analgesic agents as antipyrine and local anesthetics as lidocaine, dibucaine, and benzocaine.

Topical treatment of ear infections is frequently considered adjunctive, with concomitant systemic treatment with orally administered antibiotics also undertaken.

Liquid ear preparations of the anti-inflammatory agents hydrocortisone and dexamethasone sodium phosphate are prescribed for their effects against the swelling and inflammation which frequently accompany allergic and irritative manifestations of the ear as well as for the inflammation and pruritus which sometimes follow treatment of ear infections. In the latter instance, some physicians prefer the use of corticosteroids in ointment form, packaged in ophthalmic tubes. These packages allow the placement of small amounts of ointment in the ear canal with a minimum of waste. Many of the commercially available products used in this manner are labeled "eye-ear" to indicate their dual use.

Solutions of hydrogen peroxide, alcohol rubbing compound, and acetic acid (5%) in ethyl alcohol (85%) are frequently employed as ear rinses to prevent infection or irritation following such activities as swimming.

Pain in the ear frequently accompanies ear infection or inflamed or swollen ear tissue. Topical analgesic agents generally are employed together with internally administered analgesics, as aspirin, and other agents, as anti-infectives, to combat the cause of the problem.

Topical analgesics for the ear are usually solutions and frequently contain the analgesic antipyrine and the local anesthetic benzocaine in a vehicle of propylene glycol or anhydrous gly-

cerin (e.g., Auralgan Otic Solution, Ayerst). Again, these hygroscopic vehicles reduce the swelling of tissues (and thus some pain) and the growth of microorganisms by drawing moisture from the swollen tissues into the vehicle. These preparations are commonly employed to relieve the symptoms of acute otitis media. Examples of some commercial otic preparations are presented in Table 13-1.

As determined on an individual product basis, some liquid otic preparations require preservation against microbial growth. When preservation is required, such agents as chlorobutanol (0.5%), thimerosal (0.01%), and combinations of the parabens are commonly used. Antioxidants, as sodium bisulfite, and other stabilizers are also included in otic formulations, as required.

Ear preparations are usually packaged in small (5 to 15 mL) glass or plastic containers with a dropper.

Nasal Preparations

The vast majority of preparations intended for intranasal use contain adrenergic agents and are employed for their decongestant activity on the nasal mucosa. Most of these preparations are in solution-form, and are administered as nose drops or sprays; however, a few are available as nasal jellies. Examples of products for intranasal use are shown in Figure 13-1 and presented in Table 13-2.

Nasal Decongestant Solutions

Most nasal decongestant solutions are aqueous preparations, rendered isotonic to nasal fluids (approximately equivalent to 0.9% sodium chloride), buffered to maintain drug stability while approximating the normal pH range of the nasal fluids (pH 5.5 to 6.5), and stabilized and preserved as required. The antimicrobial preservatives used are the same as those used in preserving ophthalmic solutions. The concentration of adrenergic agent in the majority of nasal decongestant solutions is quite low, ranging from about 0.05 to 1.0%. Certain commercial solutions which are available for both pediatric and adult use, are generally available in two strengths, the pediatric strength being approximately one-half of the adult strength.

Nasal decongestant solutions are employed in

EXHIBIT H



US005164194A

United States Patent [19][11] **Patent Number:** **5,164,194****Hettche**[45] **Date of Patent:** **Nov. 17, 1992**[54] **AZELASTINE CONTAINING
MEDICAMENTS**[75] **Inventor:** **Helmut Hettche, Dietzenbach, Fed
Rep. of Germany**[73] **Assignee:** **Asta Pharma AG, Fed. Rep. of
Germany**[21] **Appl. No.:** **551,644**[22] **Filed:** **Jul. 12, 1990**

2,457,024 12/1948 Arp 248/108
 2,995,308 8/1961 Ashkencz 239/302
 3,813,384 5/1974 Vogelsang 546/133
 4,704,387 11/1987 Engel et al. 514/212
 4,769,369 9/1988 Thomas et al. 514/234.5

FOREIGN PATENT DOCUMENTS

2164058 7/1972 Fed. Rep. of Germany 546/133
 3530793 3/1986 Fed. Rep. of Germany 514/212
 1377231 1/1972 United Kingdom

OTHER PUBLICATIONS

Negwer, Organic-Chemicals, Drugs and Their Syn-
 onyms, vol. II, (1987) p. 1145
 European Search Report
 Org.-Chem. drugs and their synonyms, vol. III, No.
 6496 (1987).
 Arzneimittel. Fortschritte 1972-1985, pp. 936 and 939
 (1977).

Primary Examiner—Thurman K. Page*Assistant Examiner*—Neil S. Levy*Attorney, Agent, or Firm*—Cushman, Darby & Cushman

[57]

ABSTRACT

A medicament for nasal use or for use in the eye which
 contains as active ingredient azelastine or a physiologi-
 cally acceptable salt

12 Claims, No Drawings**Related U.S. Application Data**[63] Continuation of Ser. No. 268,772, Nov. 9, 1988, aban-
doned[30] **Foreign Application Priority Data**

Nov. 13, 1987 [DE] Fed. Rep. of Germany 3738681

[51] **Int. Cl.** A61K 9/14; A61K 31/55[52] **U.S. Cl.** 424/489; 424/43;

424/45; 424/464; 424/422; 514/212

[58] **Field of Search** 424/43, 464, 422, 45,
424/489; 514/212; 222/394; 141/24; 239/302;
248/108[56] **References Cited****U.S. PATENT DOCUMENTS**

1,585,564 1/1875 Barnes 141/24
 2,119,643 6/1938 Mendl 222/394
 2,136,940 11/1938 Ehbrecht 222/394

5,164,194

1

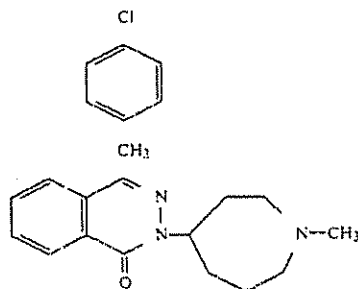
AZELASTINE CONTAINING MEDICAMENTS

This is a continuation of application Ser No 07/268,72, filed Nov. 9, 1988, now abandoned.

The present invention relates to the treatment of nasal and eye tissues with azelastine

BACKGROUND OF THE INVENTION

Azelastine is a phthalazinone derivative having the following structural formula:



The chemical designation is: 4-(4-chlorobenzyl)-2-(perhydro-1-methyl-azepine-4-yl)-1-(2H)phthalazinone. Azelastine is used in particular for prophylactic treatment of asthma. Azelastine also has anti-allergic and antihistamine properties, see German Patent No. 21 64 058

SUMMARY OF THE INVENTION

It has now been found that azelastine and its physiologically acceptable salts display particularly advantageous and surprising effects when the corresponding formulations are applied directly in the nose and/or to the conjunctival sac of the eye.

Elimination or marked relief has thus been achieved not only in allergy-related rhinitis, but also in the normal common cold (caused, for example, by rhinoviruses) as well as in the vasomotor cold and the symptoms of illness triggered thereby.

It is surprising in this context that local nasal application also has a favorable effect on the mucous membrane of the eye (elimination or relief of reddening of the eye and of eye irritation) so that the additional use of eye drops is frequently superfluous.

Other indications for the application/use of the invention are, for example: non-specific conjunctivitis, allergy-related conjunctivitis, allergic blepharodema, catarrhal conditions in the eye or nose, coryza.

Surprisingly, in addition, none of the tiredness that arises with other applications was observed with use according to the invention.

Furthermore the invention provides a way to overcome problems which arise because of azelastine's exceptionally penetrating, bitter taste. The degree of the bitter taste is so intense that it is even found to be unpleasant in a dilution of 1 : 706. This problem has hitherto prevented oral application of azelastine solutions, since patients refuse to take such azelastine solutions or suspensions. It was surprisingly found in trial subjects that this bitter taste was no longer in evidence when the azelastine formulations of the invention were sprayed into the nose. As a result, it is possible in this manner to apply solutions or suspensions of azelastine and its salts nasally without taste impairment. Moreover the bitter

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taste is barely perceptible when the sprayed azelastine solution or suspension runs down into the pharynx.

Therefore, the object of the present invention is to provide a well tolerated and improved remedy based on azelastine or its salts for the treatment both of the allergy-related and vasomotor-related conditions as well as rhino virus-related cold and its accompanying symptoms.

A further object of the present invention is to provide medical formulations which are adapted to direct application to nasal and eye tissues.

The preferred embodiment of the invention is a sterile and stable aqueous solution of azelastine or one or more of its salts which can be used in the form of drops, ointments, creams, gels, insufflatable powders or, in a particularly preferred embodiment, in the form of a spray (preferably a nasal spray). The spray can be formed by the use of a conventional spray-squeeze bottle or a pump vaporizer. In addition, it is also possible to use compressed gas aerosols. For example 0.03 to 3 mg of azelastine base should be released per individual actuation.

Through the use of nasal drops or a nasal spray, the dosage of azelastine required for the treatment of the cold is lowered approximately tenfold and hence the incidence of the appearance of side effects is considerably lower than in the case of the application of azelastine in orally taken dosage forms such as tablets or syrups which distribute the active substance throughout the entire body. In the treatment of a banal illness such as a cold, a low incidence of side effects is particularly important and thus represents a considerable medical advance.

Solvents which may preferably be used for the formulations of the invention are: water, saturated aliphatic mono and polyvalent alcohols which contain 2-3 carbon atoms (for example ethanol, isopropanol, 1,2-propylene glycol, glycerine), liquid polyglycols (molecular weight 200 to 600).

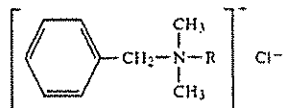
The solvent used is preferably water or mixtures of water with other physiologically acceptable solvents (for example those mentioned above). Preferably, the amount of the latter solvent in the aqueous mixture should not exceed 15% by weight.

The solutions or formulations preferably contain preservatives and stabilizers. These include, for example: ethylene diamine tetra-acetic acid (edetate) and their alkali salts (for example dialkali salts such as disodium salt, calcium salt, calcium-sodium salt), lower alkyl p-hydroxybenzoates, chlorhexidine (for example in the form of the acetate or gluconate), phenyl mercury borate. Furthermore, it is possible, for example, to use sodium-(2-ethylmercurithio)-benzoate generally known as "thimerosal" which may be present in an amount of 0.001 to 0.05, preferably from 0.005 to 0.02, for example 0.01% (weight/volume in liquid formulations, otherwise weight/weight). Other suitable preservatives are: pharmaceutically useful quaternary ammonium compounds, for example cetylpyridinium chloride, tetradecyltrimethyl ammonium bromide, generally known as "cetrimide", benzyldimethyl-[2-[2-[p-(1,1,3,3-tetramethyl-butyl)]phenoxy]ethoxy]-ammonium chloride, generally known as "benzethonium chloride" and myristyl-picolinium chloride. Each of these compounds may be used in a concentration of 0.002 to 0.05, for example 0.02% (weight/volume in liquid formulations, otherwise weight/weight). Preferred preserva-

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tives among the quaternary ammonium compounds are, however, alkylbenzyl dimethyl ammonium chloride and mixtures thereof for example the compounds generally known as "benzalkonium chloride". These latter consist of a mixture of the compounds of formula,



in which R represents an alkyl group having the formula $\text{C}_n\text{H}_{2n+1}$, wherein n represents a whole number from 8 to 18. The use of a mixture of compounds in which n represents 10 to 14 is particularly preferred and in particular the special compound in which $\text{R}=\text{C}_{12}\text{H}_{25}$ "Benzalkonium chloride" and the compounds of the above formula can be used in concentrations of 0.005 to 0.10, preferably of 0.005 to 0.05, for example of 0.01% (weight/volume for liquid formulations, otherwise weight/weight) and they may optionally be used in combination with 0.2 to 2.0, for example 0.4% (weight/volume) of 2-phenylethanol.

The formulations of the invention (solutions, suspensions as well as oily solutions or suspensions, ointments, emulsions, creams, gels, dosage aerosols) contain 0.0005 to 2, preferably 0.001 to 1, in particular 0.003 to 0.5% (weight/weight) of azelastine (related to the free azelastine base). Should the azelastine be present as a salt, the amounts should be recalculated as necessary to give the amounts of azelastine itself mentioned above. In the case of the eye drops, the same azelastine concentrations apply as in the case of the nasal forms.

In the case of powders, the concentration of azelastine base is 0.0005 to 2 percent by weight related to the solid carrier substances.

In the case of solutions, the dosage per nostril is, for example, 0.01 to 0.2 ml, in particular 0.05 to 0.15 ml. Such a dosage should be applied once to several times, preferably 1 to 5 times daily (optionally also hourly).

In the case of use at the eye (eye drops) the dosage is for example 1 drop (about 0.05 ml) of the solution or corresponding amounts of the semi-solid formulation forms.

Possible acid components for azelastine salts are, for example: hydrohalic acids (HCl, HBr), sulphuric acid, phosphoric acids (H_3PO_4 , metaphosphoric acid, polyphosphoric acids), nitric acid, organic mono-, di- or tricarboxylic acids of aliphatic, alicyclic, aromatic or heterocyclic organic acids (embonic acid, citric acid, tartaric acid), aliphatic and aromatic sulfonic acids (for example camphorsulfonic acid).

The total amounts of preservatives in the formulations (solutions, ointments, etc.) is between 0.001 to 0.10, preferably 0.01 g per 100 ml of solution/suspension or 100 g of formulation.

In the case of preservatives, the following amounts of individual substances can, for example, be used:

thimerosal 0.002-0.02%;

benzalkonium chloride 0.002 to 0.02% (in combination with thimerosal the amount of thimerosal is, for example = 0.002 to 0.005%);

chlorhexidine acetate or gluconate 0.01 to 0.02%;

phenyl mercuric/nitrate, borate, acetate 0.002-0.004%;

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p-hydroxybenzoic acid ester (for example a mixture of the methyl ester and propyl ester 7 : 3); 0.05-0.15, preferably 0.1%.

The preservative used is preferably a combination of edetic acid (for example as the disodium salt) and benzalkonium chloride. In this combination, the edetic acid is used in a concentration of 0.05 to 0.1%, benzalkonium chloride being used in a concentration of 0.005 to 0.05%, preferably 0.01%.

In the case of solutions/suspensions reference is always made to percent by weight/volume, in the case of solid or semi-solid formulations to percent by weight/weight of the formulation.

Further auxiliary substances which may, for example, be used for the formulations of the invention are: polyvinyl pyrrolidone, sorbitan fatty acid esters such as sorbitan trioleate, polyethoxylated sorbitan fatty acid esters (for example polyethoxylated sorbitan trioleate), sorbimacrogol oleate, synthetic amphotensides (triton), ethylene oxide ethers of octylphenolformaldehyde condensation products, phosphatides such as lecithin, polyethoxylated fats, polyethoxylated oleotriglycerides, polyethoxylated fatty alcohols. In this context, polyethoxylated means that the relevant substances contain polyoxyethylene chains, the degree of polymerization of which is generally between 2 to 40, in particular between 10 to 20. These substances are preferably used to improve the solubility of the azelastine components.

In the case of dosage forms containing water, it is optionally possible to use additional isotonicization agents. Isotonicization agents which may, for example, be used are: saccharose, glucose, glycerine, sorbitol, 1,2-propylene glycol, NaCl.

The isotonicization agents adjust the osmotic pressure of the formulations to the same osmotic pressure as nasal secretion. For this purpose these substances are in each case to be used in such amount that, for example, in the case of a solution, a reduction in the freezing point of 0.50° to 0.56° C is attained in comparison to pure water. In Example 1, for instance, such substances would be used in such an amount which is iso-osmotic with 68 g of sodium chloride (0.68%).

In Example 1, it is possible to use instead of NaCl per 100 ml of solution, for example:

Glucose $1\text{H}_2\text{O}$ 3.81 g ; saccharose 6.35 g ; glycerine 2.2 g ; 1,2-propylene glycol 1.617 g ; sorbitol 3.84 g (in the case of mixtures of these substances correspondingly less may optionally be used).

Moreover, it is possible to add thickening agents to the solutions to prevent the solution from flowing out of the nose too quickly and to give the solution a viscosity of about 1.5 to 3, preferably 2 mPa.s. Such thickening agents may, for example, be: cellulose derivatives (for example cellulose ether) in which the cellulose-hydroxy groups are partially etherified with lower unsaturated aliphatic alcohols and/or lower unsaturated aliphatic oxalcohols (for example methyl cellulose, carboxymethyl cellulose, hydroxypropylmethylcellulose), gelatin, polyvinylpyrrolidone, tragacanth, ethoxose (water soluble binding and thickening agents on the basis of ethyl cellulose), alginic acid, polyvinyl alcohol, polyacrylic acid, pectin and equivalent agents. Should these substances contain acid groups, the corresponding physiologically acceptable salts may also be used.

In the event of the use of hydroxypropyl cellulose, 0.1% by weight are, for example, used for this purpose.

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It is also possible to add to the formulations buffer substances such as citric acid / sodium hydrogensulphate borate buffer, phosphates (sodium hydrogenorthophosphate, disodium hydrogenphosphate), tromethamol or equivalent conventional buffers in order, for example, to adjust the formulation to a pH value of 6 to 7.5, preferably 6.5 to 7.1

The amount of citric acid is, for example, 0.01 to 0.14, preferably 0.04 to 0.05 g, the amount of disodium hydrogenphosphate 0.1 to 0.5, preferably 0.2 to 0.3 g per 100 ml of solution. The weights given relate in each case to the anhydrous substances

In the case of solutions and suspensions, the maximum total concentration of active agent and buffer should be less than 5%, in particular less than 2% (weight/volume).

For the nasal application a solution or suspension is preferably used which is applied as an aerosol, i.e. in the form of a fine dispersion in air or in another conventional carrier gas, for example by means of a conventional pump vaporizer.

Application as a dosage aerosol is, however, also possible. Dosage aerosols are defined as being pressure packings which contain the azelastine or its salts in the form of a solution or suspension in a so-called propellant. Propellants are pressurized liquid chlorinated, fluorinated hydrocarbons or mixtures of various chlorinated, fluorinated hydrocarbons as well as propane, butane, isobutane or mixtures of these among themselves or with chlorinated, fluorinated hydrocarbons which are gaseous at atmospheric pressure and room temperature. The pressure packing has a dosage valve which, on actuation, releases a defined amount of the solution or suspension of the medicament. The subsequent very sudden vaporization of the propellant tears the solution or suspension of azelastine into the finest droplets or minute particles which can be sprayed into the nose or which are available for inspiration into the nose. Certain plastic applicators are used to actuate the valve and to convey the sprayed suspension into the nose. Propellants that may, however, also be used are: CO₂, nitrous oxide and compressed air.

In the case of application as an aerosol, it is also possible to use a conventional adapter.

When suspensions are used, the maximum particle size of the solid substances (azelastine + auxiliary substances) should not exceed 30 µm.

In the case of use in the form of an insufflatable powder, the maximum particle size of the substances should not be greater than 20 µm.

What occurs is, for example, a vaporizing of solid azelastine or its salts. In this case the azelastine or its salt is, for example, mixed with inert carrier substances or drawn up onto inert carrier substances. Carrier substances which may, for example, be used are: sugars such as glucose, saccharose, lactose and fructose. Also starches or starch derivatives, oligosaccharides such as dextrans, cyclodextrins and their derivatives, polyvinylpyrrolidone, alginic acid, tylose, silicic acid, cellulose, cellulose derivatives (for example cellulose ether), sugar alcohols such as mannitol or sorbitol, calcium carbonate, calcium phosphate. The concentration of azelastine is 1 part by weight of azelastine to 50 to 200,000 parts by weight of carrier substance (0.0005 to 2% of azelastine).

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DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The invention is illustrated by the following examples

EXAMPLE 1

Nasal spray or nasal drops or eye drops with 0.1% azelastine hydrochloride as active ingredient

The following are dissolved, in the following order, into 9.00 kg of water: 10 g of azelastine hydrochloride, 5 g of edetic acid disodium salt 2 H₂O, 68 g of sodium chloride, 1.25 g of alkyl-benzylidimethylammonium chloride (benzalkonium chloride), 4.38 g of citric acid, 64.8 g of sodium monohydrogen-phosphate 12 H₂O as well as 10 g of hydroxypropylmethyl cellulose.¹

¹ Commercially available product, for example methocel E4M premium

The solution obtained is diluted to 10.05 kg = 10 liters with water. The solution is filtered through a membrane filter of pore size 0.2 µm after careful mixing, the first 500 ml of filtrate being discarded. The filtrate has a pH value of 6.8 ± 0.3. This is filled into plastic bottles which are closed with a conventional spray insert or into plastic or glass bottles which are closed with a conventional pump sprayer. In the latter case, pumps with nasal spray inserts are, for example used, which spray about 0.14 ml of solution per actuation. In this manner, 0.14 mg of azelastine hydrochloride are sprayed into the nose per actuation in the form of the solution.

If the above obtained filtrate is filled into the bottles with dropper pipettes conventionally used for nasal drops or eye drops, the solution can be dripped into the nose or eye using a dropper pipette.

EXAMPLE 2

Nasal ointment with 0.1% of azelastine hydrochloride

5 kg of polyoxyethylene stearate², 8 kg of cetylstearyl alcohol (Lanette O), 20 kg of white Vaseline, 15 kg of liquid paraffin and 0.5 kg of silicon oil are melted together in a heatable vessel. 126 g of p-hydroxybenzoic acid methyl ester and 53 g of p-hydroxybenzoic acid propyl ester are dissolved in the melt (temperature of the melt 80° C). Subsequently, a solution heated to 70° C. of 0.1 kg of azelastine hydrochloride, 140 g of p-hydroxybenzoic acid methyl ester and 60 g of p-hydroxybenzoic acid propyl ester in 51.021 kg of purified water are emulsified with the aid of a high speed stirrer and the emulsion obtained is stirred until cold and repeatedly homogenized at regular time intervals.

² Polyoxyethylene-40 stearate, solid, white to cream-colored mass, D₂₅ ca 1.1, F 40°-44° C. Solidification point ca 41° C.

The ointment is filled into tubes which have a tubular extension beyond the thread and are thus particularly suitable for applying the ointment into the nose.

EXAMPLE 3

Dosage aerosol giving off 0.5 mg of azelastine hydrochloride per stroke

About 8.0 kg of a mixture of 70 parts by weight of difluorodichloromethane and 30 parts by weight of 1,2-dichlorotetrafluoroethane are cooled to about -55° C. in an appropriate cooling vessel. A mixture of 0.086 kg of precooled sorbitantriolate and 0.8600 kg of precooled trichlorofluoromethane are dissolved with stirring into this mixture at -55° C. 0.0688 kg of micronized azelastine hydrochloride and 0.0688 kg of micron-

5,164,194

7

ized lactose are then incorporated in portions into the solution thereby obtained with intensive stirring. The total weight of the suspension thereby obtained is made up to 9.547 kg through addition of more of the mixture of 70 parts by weight of difluorodichloromethane and 30 parts by weight of 1,2-dichlorotetrafluoroethane cooled to about -55°C .

Following closure of the cooling vessel the suspension is again cooled to about -55°C under intensive stirring. It is then ready to be filled.

With continued stirring the suspension is filled into the conventional suitable aluminum monobloc tins. The monobloc tins are closed immediately after the suspension has been filled using conventional dosage valves which release 0.05 ml of suspension per valve actuation. Actuation of the valve thus releases 0.5 mg of azelastine hydrochloride. Presentation is effected in conjunction with a conventional applicator which permits introduction of the active substance into the nose of the patient.

EXAMPLE 4

Eye drops with 0.05% of azelastine hydrochloride

140 g of polyvinylalcohol (trade name for example: Mowiol 26-88 / Hoechst AG, Frankfurt 80) are stirred into 4 liters of cold water for injection purposes, the suspension is heated to 90°C and left at this temperature for 45 minutes. After cooling, the solution obtained is mixed with the following solutions:

5 g of azelastine hydrochloride in 1 liter of water for injection purposes, 0.2 g of phenyl mercuric nitrate in 2 liters of water for injection purposes, 70 g of sodium chloride in 1 liter of water for injection purposes.

The mixture is adjusted to a pH value of 6.8 through addition of 0.1 N sodium hydroxide solution, mixed with a solution of 15 g of sodium dihydrogen phosphate $2\text{H}_2\text{O}$ and 21 g of disodium hydrogen phosphate $2\text{H}_2\text{O}$ in 1 liter of water for injection purposes and filled up to 10 liters with water for injection purposes.

Following careful mixing the solution is filtered through a membrane filter of pore size $0.2\text{ }\mu\text{m}$ with glass fiber pre-filter and filled into sterile eye drop bottles under aseptic conditions after discarding a first 500 ml of filtrate.

What is claimed is:

8

1. A method for the treatment of irritation or disorders of the nose and eye which comprises applying directly to nasal tissues or to the conjunctival sac of the eyes a medicament which contains a member selected from the group consisting of azelastine and its physiologically acceptable salts.

2. A method as set forth in claim 1 in which the medicament contains 0.0005 to 2% (weight/weight) of azelastine or an amount of a physiologically acceptable salt of azelastine which contains 0.0005 to 2% (weight/weight) azelastine.

3. A method as set forth in claim 2 in which the medicament contains 0.001 to 1% (weight/weight) of azelastine or an amount of a physiologically acceptable salt of azelastine which contains 0.001 to 1% (weight/weight) azelastine.

4. A method as set forth in claim 1 in which the medicament contains 0.003 to 0.5% (weight/weight) of azelastine or an amount of a physiologically acceptable salt of azelastine which contains 0.003 to 0.5% (weight/weight) azelastine.

5. A method as set forth in claim 1 in which the medicament contains a pharmaceutically usable preservative in an amount of 0.001 to 0.1%.

6. A method as set forth in claim 1 in which the medicament is a solution.

7. A method as set forth in claim 1 in which the medicament is an aqueous solution.

8. A method as set forth in claim 1 in which the medicament is a solution which contains 0.001 to 0.05% (weight/volume of solution) of sodium-2-(ethylmercurithio)-benzoate or 0.001 to 0.1% (weight/volume of solution) of alkylbenzyltrimethyl ammonium chloride.

9. A method as set forth in claim 1 in which the medicament is applied by spraying.

10. A method as set forth in claim 1 in which the medicament is applied as drops.

11. A method as set forth in claim 1 in which the medicament is a powder.

12. A method for the treatment of a patient suffering from allergy-related, or vasomotor or rhino-related colds or symptoms which comprises applying directly to the patient's nasal tissues or to the conjunctival sac of the patient's eye a medicament which contains a member selected from the group consisting of azelastine and its physiologically acceptable salts.

* * * * *

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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

PATENT NO. : 5,164,194
ISSUED : November 17, 1992
INVENTOR(S) : Helmut Hettche
PATENT OWNER : Asta Medica, AG

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

349 days

from November 17, 2009, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the Patent and Trademark Office to be affixed this 27th day of February 1998.

Bruce A. Lehman

Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and

EXHIBIT I

EXHIBIT I
REDACTED
IN ITS ENTIRETY

EXHIBIT J

EXHIBIT J
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EXHIBIT K

EXHIBIT K
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EXHIBIT L

EXHIBIT L
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EXHIBIT M

PDR®
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EDITION
1987

PHYSICIANS' DESK REFERENCE®

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Product Information

Always consult

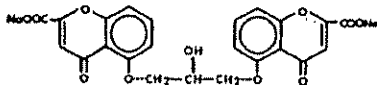
Fisons—Cont.

NASALCROM® NASAL SOLUTION
[näs 'äl-krom "]
(cromolyn sodium nasal solution, USP)

DESCRIPTION

Each milliliter of NASALCROM® Nasal Solution (cromolyn sodium nasal solution, USP) contains 40 mg cromolyn sodium in purified water with benzalkonium chloride 0.01% and EDTA (disodium edetate) 0.01% added to stabilize and to provide antimicrobial protection for the solution. NASALCROM possesses a natural pH of 4.5–6.5 and negligible titratable acidity. Chemically, cromolyn sodium is the disodium salt of 1,3-bis(2-carboxychromon-5-yloxy)-2-hydroxypropane.

The molecular structure is:



Pharmacologic Category: Mast cell stabilizer/ antiallergic
Therapeutic Category: Antiallergic

After priming the delivery system for NASALCROM, each actuation of the unit delivers a metered spray containing 5.2 mg of cromolyn sodium. The contents of one nasal spray bottle delivers at least 100 sprays.

CLINICAL PHARMACOLOGY

In vitro and *in vivo* animal studies have shown that cromolyn sodium inhibits the degranulation of sensitized mast cells which occurs after exposure to specific antigens. Cromolyn sodium inhibits the release of histamine and SRS-A (the slow-reacting substance of anaphylaxis). Rhinitis induced by the inhalation of specific antigens can be inhibited to varying degrees by pretreatment with NASALCROM.

Another activity demonstrated *in vitro* is the capacity of cromolyn sodium to inhibit the degranulation of non-sensitized rat mast cells by phospholipase A and the subsequent release of chemical mediators. An additional *in vitro* study showed that cromolyn sodium did not inhibit the enzymatic activity of released phospholipase A on its specific substrate. Cromolyn sodium has no intrinsic bronchodilator, antihistaminic or anti-inflammatory activity.

Cromolyn sodium is poorly absorbed from the gastrointestinal tract. After instillation of NASALCROM, less than 7% of the total dose administered is absorbed and is rapidly excreted unchanged in the bile and urine. The remainder of the dose is expelled from the nose, or swallowed and excreted via the alimentary tract.

INDICATIONS

NASALCROM is indicated for the prevention and treatment of the symptoms of allergic rhinitis.

CONTRAINDICATIONS

NASALCROM is contraindicated in those patients who have shown hypersensitivity to any of the ingredients.

PRECAUTIONS

General: Some patients may experience transient nasal stinging and/or sneezing immediately following instillation of NASALCROM. Except in rare occurrences, these experiences have not caused discontinuation of therapy.

In view of the biliary and renal routes of excretion for cromolyn sodium, consideration should be given to decreasing the dosage or discontinuing the administration of the drug in patients with impaired renal or hepatic function.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long term studies in mice (12 months intraperitoneal treatment followed by 6 months observation), hamsters (12 months intraperitoneal treatment followed by 12 months observation), and rats (18 months subcutaneous treatment) showed no neoplastic effect of cromolyn sodium.

No evidence of chromosomal damage or cytotoxicity was obtained in various mutagenesis studies.

No evidence of impaired fertility was shown in laboratory animal reproduction studies.

Pregnancy: Pregnancy Category B. Reproduction studies with cromolyn sodium administered parenterally to pregnant mice, rats, and rabbits in doses up to 338 times the human clinical doses produced no evidence of fetal malformations. Adverse fetal effects (increased resorptions and decreased fetal weight) were noted only at the very high parental doses that produced maternal toxicity. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Drug Interaction During Pregnancy: Cromolyn sodium and isoproterenol were studied following subcutaneous injections in pregnant mice. Cromolyn sodium alone in doses of 60 to 640 mg/kg (38 to 338 times the human dose) did not cause significant increases in resorptions or major malformations.

Isoproterenol alone at a dose of 2.7 mg/kg (90 times the human dose) increased both resorptions and malformations. The addition of cromolyn sodium (338 times the human dose) to isoproterenol (90 times the human dose) appears to have increased the incidence of both resorptions and malformations.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when NASALCROM is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 6 years have not been established.

ADVERSE REACTIONS

The most frequent adverse reactions occurring in the 430 patients included in the clinical trials with NASALCROM were sneezing (1 in 10 patients), nasal stinging (1 in 20), nasal burning (1 in 25), and nasal irritation (1 in 40). Headaches and bad taste were reported in about 1 in 50 patients. Epistaxis, postnasal drip, and rash were reported in less than one percent of the patients. One patient in the clinical trials developed anaphylaxis.

Adverse reactions which have occurred in the use of other cromolyn sodium formulations for inhalation include angioedema, joint pain and swelling, urticaria, cough, and wheezing. Other reactions reported rarely are serum sickness, periarthritis vasculitis, polymyositis, pericarditis, photodermatitis, exfoliative dermatitis, peripheral neuritis, and nephrosis.

DOSAGE AND ADMINISTRATION

The dose for adults and children 6 years and older is one spray in each nostril 3–4 times daily at regular intervals. If needed, this dose may be increased to one spray to each nostril 6 times daily. The patient should be instructed to clear the nasal passages before administering the spray and should inhale through the nose during administration.

In the management of seasonal (pollenotic) rhinitis, and for prevention of rhinitis caused by exposure to other types of specific inhalant allergens, treatment with NASALCROM will be more effective if started prior to expected contact with the offending allergen. Treatment should be continued throughout the period of exposure, i.e., until the pollen season is over or until exposure to the offending allergen is terminated.

In the management of perennial allergic rhinitis, the effects of treatment with NASALCROM may become apparent only after two to four weeks of treatment. The concomitant use of antihistamine and/or nasal decongestant may be necessary during the initial phase of treatment, but the need for this type of medication should diminish and may be eliminated when the full benefit of NASALCROM is achieved.

HOW SUPPLIED

Each 13 ml NASALCROM Nasal Solution (cromolyn sodium, nasal solution, USP) spray bottle contains 520 mg (40 mg/ml) of cromolyn sodium and is to be used with the Nasalmatic® metered spray device. The Nasalmatic device consists of a pump unit, plastic case and a patient leaflet of instructions. The cleaning of this device is not recommended. The pump device should be replaced at six month intervals. NASALCROM should be stored at controlled room temperature (15°–30°C).

NDC 0585-0671-02 Complete pack (13 ml bottle,

metered spray device)

NDC 0585-0671-01 Refill (13 ml bottle)

Caution: Federal law prohibits dispensing without prescription.

Rev. 3/85
FC7102C

OPTICROM® 4%

[op 'ti-krom "]

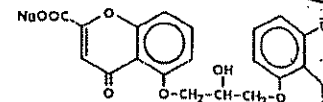
(cromolyn sodium ophthalmic solution, USP)
Ophthalmic Solution

DESCRIPTION

Each milliliter of OPTICROM 4% Ophthalmic Solution (cromolyn sodium ophthalmic solution, USP) contains 40 mg cromolyn sodium in purified water with 0.01% benzalkonium chloride to preserve and 0.1% EDTA (edetate disodium, USP) to stabilize the solution. OPTICROM is a clear, colorless, sterile solution with a pH of 4.0–7.0. It is intended for topical administration to the eye.

Chemically, cromolyn sodium is the disodium salt of 1,3-bis(2-carboxychromon-5-yloxy)-2-hydroxypropane. Its chemical structure is:

[See Chemical Formula at top of next column].



Pharmacologic Category: Mast cell stabilizer
Therapeutic Category: Antiallergic

CLINICAL PHARMACOLOGY

In vitro and *in vivo* animal studies have shown that cromolyn sodium inhibits the degranulation of sensitized mast cells which occurs after exposure to specific antigens. Cromolyn sodium acts by inhibiting the release of histamine (slow-reacting substance of anaphylaxis) from the mast cells. Another activity demonstrated *in vitro* is the capacity of cromolyn sodium to inhibit the degranulation of non-sensitized rat mast cells by phospholipase A and the subsequent release of chemical mediators. Another study showed that cromolyn sodium did not inhibit the enzymatic activity of released phospholipase A on its specific substrate. Cromolyn sodium has no intrinsic vasoconstrictor, minic or anti-inflammatory activity.

Cromolyn sodium is poorly absorbed. When instilled into the eyes of normal rabbits, less than 0.07% of the administered dose was absorbed into the systemic circulation.

A study on corneal epithelial wound healing in rabbits failed to demonstrate any significant difference in the rate of corneal re-epithelialization between cromolyn sodium ophthalmic solution, sterile saline solution, and an ophthalmic corticosteroid.

INDICATIONS AND USAGE

OPTICROM is indicated in the treatment of certain ocular disorders referred to by the terms vernal conjunctivitis, vernal conjunctivitis, giant papillary conjunctivitis, vernal keratitis, and allergic keratoconjunctivitis. The etiologic factors are unknown, but common allergens and contact lenses have been implicated. Symptomatic response to therapy (decreased itching, redness, and discharge) is usually evident within a few days, but longer treatment for up to six weeks may be required. Once symptomatic improvement has been achieved, therapy should be continued for as long as to sustain improvement.

If required, corticosteroids may be used concomitantly with OPTICROM.

Users of soft (hydrophilic) contact lenses should remove wearing lenses while under treatment with OPTICROM. Wear can be resumed within 24 hours after discontinuation of the drug.

CONTRAINDICATIONS

OPTICROM is contraindicated in those patients who have shown hypersensitivity to cromolyn sodium or to any of the other ingredients.

As with all ophthalmic preparations containing boric acid, patients are advised not to wear contact lenses during treatment with OPTICROM.

PRECAUTIONS

General: Patients may experience a transient burning sensation following application of OPTICROM. The recommended frequency of administration should not be exceeded. The dose for adults and children is 1–2 drops each eye 4–6 times a day at regular intervals.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long term studies in mice (12 months intraperitoneal treatment followed by six months observation), hamsters (12 months intraperitoneal treatment followed by 12 months observation), and rats (18 months subcutaneous treatment) showed no neoplastic effect of cromolyn sodium. No evidence of chromosomal damage or cytotoxicity was obtained in various mutagenesis studies.

No evidence of impaired fertility was shown in laboratory animal reproduction studies.

Pregnancy: Pregnancy Category B. Reproduction studies with cromolyn sodium administered parenterally to pregnant mice, rats and rabbits in doses up to 338 times the human clinical doses produced no evidence of fetal malformations. Adverse fetal effects (increased resorption, decreased fetal weight) were noted only at the very high parental doses that produced maternal toxicity. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

EXHIBIT N

Westlaw

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 (Cite as: 179 Fed Appx 6)

Page 1

Sun Coast Merchandise Corp v CCL Products Enterprises, Inc
 C A Fed (Cal), 2006

This case was not selected for publication in the Federal Reporter NOTE: Pursuant to Fed Cir R 47.6, this order is not citable as precedent. It is public record. Please use FIND to look at the applicable circuit court rule before citing this opinion. Federal Circuit Rule 47.6 (FIND CTAF Rule 47.6)

United States Court of Appeals, Federal Circuit
SUN COAST MERCHANDISE CORP and Dilip Bhavnani, Plaintiffs-Cross Appellants,

v

CCL PRODUCTS ENTERPRISES, INC, CCL Creative Ltd, CCL Products, Ltd, and C C & L Company Ltd, Defendants-Appellants
 Nos. 05-1173, 05-1216.

April 21, 2006

Rehearing Denied June 1, 2006

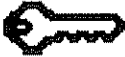
Background: Competitor filed a declaratory judgment action, seeking determination that patent for portable hand-held calculator with pivoting lid was invalid or not infringed by competitor's accused calculators. The United States District Court for the Central District of California granted summary judgment of non-infringement of patent. Patent holder appealed, and competitor cross-appealed denial of its motion for attorney fees.

Holdings: After reinstating review, 135 Fed.Appx. 429, the Court of Appeals, Prost, Circuit Judge, held that:

- (1) trunnion in patent was broad enough to include a projection with a recess;
- (2) damping means meant damping drum, helical coil spring, and damping grease which performed the functions of biasing lid toward a rearwardly pivoted position and effectuating a controlled pivotal motion of lid;
- (3) competitor's portable hand-held calculator with double flipper lid design did not infringe patent; and
- (4) denial of competitor's motion for attorney fees was neither clear error nor abuse of discretion.

Affirmed in part, vacated in part, and remanded

West Headnotes

[1] Patents 291  101(2)

291 Patents

291IV Applications and Proceedings Thereon

291k101 Claims

291k101(2) k Construction in General

Most Cited Cases

Trunnion in patent for portable hand-held calculator with pivoting lid, although required to contain a projection, was broad enough to include a projection with a recess.

[2] Patents 291  101(2)

291 Patents


291IV Applications and Proceedings Thereon

291k101 Claims

291k101(2) k Construction in General

Most Cited Cases

Damping means in patent for portable hand-held calculator with pivoting lid meant damping drum, helical coil spring, and damping grease which performed the functions of biasing lid toward a rearwardly pivoted position and effectuating a controlled pivotal motion of lid.

[3] Patents 291  236(2)

291 Patents

291XII Infringement

291XII(A) What Constitutes Infringement

291k233 Patents for Machines or Manufactures

291k236 Identity of Form

291k236(2) k Particular Devices

Most Cited Cases

Competitor's portable hand-held calculator with

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 (Cite as: 179 Fed.Appx. 6)

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double flipper lid design did not infringe patent for portable hand-held calculator with pivoting lid; unlike patented calculator, when competitor's lid structure opened, calculator's display panel was not exposed because a second portion of the housing still covered the display.

[4] Patents 291  324.53

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k324 Appeal

291k324.53 k Amendments.

Additional Proofs, and Trial of Cause Anew Most Cited Cases

District court was not obligated to provide patent holder a further opportunity to **supplement** the record, after it failed to present evidence of infringement under the doctrine of equivalents in its brief in opposition to competitor's summary judgment motion

[5] Patents 291  325.11(4)

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k325 Costs

291k325.11 Disbursements in General

291k325.11(2) Attorney Fees

291k325.11(4) k Award to

Defendant Most Cited Cases

District court's denial of competitor's motion for attorney fees in patent infringement action was neither clear error nor abuse of discretion; court found that competitor failed to establish by clear and convincing evidence actual wrongful intent or gross negligence by patent holder, that patent holder's counsel had not multiplied proceedings unreasonably and vexatiously, and that conduct of patent holder and its counsel was not sufficiently egregious to warrant sanctions 28 U.S.C.A. § 1927; 35 U.S.C.A. § 285

Patents 291  328(2)

291 Patents

291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents

291k328 Patents Enumerated

291k328(2) k Original Utility Most Cited

Cases

6,178,085 Not Infringed

*7 Before MICHEL, Chief Judge, LINN, and PROST, Circuit Judges

PROST, Circuit Judge

**1 CCL Products Enterprises, Inc, CCL Creative Ltd, CCL Products, Ltd, and C.C. & L. Co Ltd (collectively, "CCL") appeal from a decision of the United States District Court for the Central District of California granting summary judgment of non-infringement of U.S. Patent No. 6,178,085 (the "'085 patent") in favor of Sun Coast Merchandise Corp and Dilip Bhavnani (collectively, "Sun Coast") *Sun Coast Merch Corp. v. CCL Prods. Enters., Inc*, No SA CV 03-0991 (C D Cal Nov 22, 2004) Sun Coast cross-appeals the district court's denial of its motion for *8 attorney fees *Sun Coast Merch Corp. v. CCL Prods. Enters., Inc*, No SA CV 03-0991 (C D Cal Jan 12, 2005) ("Attorney Fees Order") Because we have clarified the construction of "trunnions" and "damping means," and several issues remain to be addressed by the district court, we *vacate* the summary judgment findings with respect to literal infringement of two of Sun Coast's calculator designs and *remand* for the district court to determine whether those two designs literally infringe the asserted claims of the '085 patent Additionally, we *affirm* the district court's summary judgment finding of noninfringement with respect to Sun Coast's third calculator design, the court's finding of noninfringement under the doctrine of equivalents with respect to all of the calculator designs at issue, and the court's denial of attorney fees

I BACKGROUND

CCL's '085 patent discloses a calculator which generally contains a housing and a "lid mechanism which pivots a flat cover of the calculator in a predetermined controlled manner between a first position[,] in which the cover forms a lid overlying the display, and a second position in which the cover is "pivoted towards the rear of the calculator so as to

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 179 Fed Appx. 6, 2006 WL 1044244 (C A Fed (Cal))
 (Cite as: 179 Fed Appx. 6)

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form a stand for tilting the calculator into an upwardly inclined ergonomic position. '085 patent, Abstract. The '085 patent specification discloses that one object of the invention is to provide a novel calculator lid mechanism that has been adapted "for controlled pivoting actuation to alternatively form a

cover for a display panel and a stand for the calculator." *Id.* at col 2, ll 61-65. Figures 4 and 5 show both positions of the lid mechanism, as a cover and alternatively, a stand.

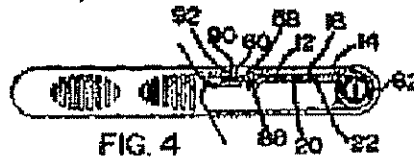
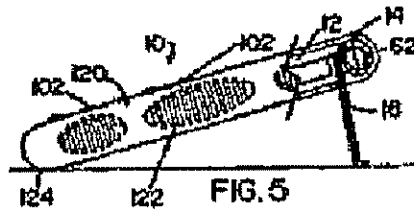


FIG. 5



After being accused by CCL of infringing the '085 patent, Sun Coast filed a declaratory judgment action that the '085 patent was invalid and/or not infringed by its accused calculators. In response, CCL filed a counterclaim for infringement of claims 1, 2, 7, 8, and 9 of the '085 patent.

Claim 1, the only independent claim asserted, is representative of the claims at issue:

1 A portable hand-held calculator, comprising:
 (a) a generally flat rectangular housing containing operating electronics and an array of calculator actuating buttons; a display panel being located on a front surface of said housing proximate said array of actuator buttons; said housing including a pair of flanges extending from opposite side edges of said housing in parallel spaced relationship; and *hinge-forming trunnions being formed on inwardly facing surfaces of said flanges;*

*2 (b) a lid structure connected to said trunnions for pivotal motion relative to said housing, said lid structure including a flat cover portion and a tubular portion formed along one edge of said flat cover portion extending between said trunnions, said tubular portion including cylindrical bores extending along the longitudinal axis thereof; and

*9 (c) a lid operating mechanism including *damping means arranged within at least one said cylindrical bore*, biasing said lid toward a rearwardly pivoted position, and effectuating a controlled pivotal motion

of said lid structure between the closed position thereof covering said display panel and the rearwardly pivoted position exposing said display panel and forming a stand for supporting said calculator in a tilted position on a horizontal surface.

Id. at col 7, ll 2-27 (emphases added)

In its *Markman* opinion, the district court construed the term "trunnions" as "pin[s] or pivot[s] usually mounted on bearings for rotating or tilting something." *Sun Coast Merch. Corp. v. CCL Prods. Enters., Inc.*, No. CV 01-0772, slip op. at 12-13 (C.D. Cal. May 1, 2003) (*"Markman Opinion"*). Based on the context of the claim language and the disclosures in the specification, however, the court limited "trunnions" to those "that project from the inwardly facing surface of the flanges." *Id.* at 13.

Sun Coast markets several different models of accused calculators. The district court separated the accused calculators according to their design into three general categories. We continue the district court's practice of referring to the accused devices in the following manner:

- (1) "original design:" including models RC2500 and original RC3000
- (2) "modified design:" including models RC2600, RC2500M, RC2700, and modified RC3000
- (3) "double flipper" or the CALC-0050 model

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See, e.g., Sun Coast Merch Corp v. CCL Prods. Enters., Inc., No SA CV 03-0991, slip op at 2 n 2 (C D Cal Oct 28, 2004) ("Summary Judgment Order")

In its opinion granting Sun Coast's motion for summary judgment of non-infringement, the district court found that CCL did not provide any admissible evidence of infringement in response to Sun Coast's motion. The "evidence" proffered consisted of: "(1) unauthenticated photographs that purport to compare the Sun Coast products to the CCL products; and (2) unauthenticated computer generated drawings of Sun Coast's products." *Id.* at 7. Thus, the district court concluded that "[h]aving submitted only these questionable exhibits with mere conclusory argument, CCL has provided no evidence to support its position of infringement. CCL's unsupported statements are wholly insufficient to raise a genuine evidentiary dispute requiring the case to go before a jury." *Id.* The district court found that CCL failed to go beyond the pleadings and provide the court with evidence of either literal infringement or "evidence of the equivalency of Sun Coast's products and the limitations in claim 1." *Id.* at 8, n 5. That failure was sufficient for the district court to find that CCL's lack of proof entitled Sun Coast to summary judgment of non-infringement on both literal infringement and infringement under the doctrine of equivalents. *Id.*

*3 The district court, however, subsequently made clear that its grant of summary judgment was not based solely on CCL's failure to present evidence of infringement, but also on its own observations of the accused devices which the court apparently disassembled on its own accord: "the Court's examination of the products at issue, coupled with CCL's failure to provide evidence to the contrary, leads to the conclusion that all elements contained in claim 1 of the '085 Patent are not present in the Sun Coast products." *Id.* at 9. The district court then proceeded to examine the disassembled accused products and make findings of fact regarding whether each of the *10 three categories of accused products literally infringe.

Specifically, the district court's analysis of infringement consisted of a single paragraph for each design type, as reproduced here:
 The original design does not embody every limitation

of claim 1. The calculators do not have projections on the inner surface of both sides of the housing about which the lid rotates. In other words, the RC2500 and RC3000 do not have flanges with hinge forming trunnions (pins or pivots) that are distinct components. Rather, the lid is attached and rotational movement about the housing is permitted by an outwardly extended attachment means on the lid structure. The support portion in the RC2500 and RC3000 rotate about an integral bore and include extensions that are fitted into the housing. Also, the RC2500 and RC3000 only appear to have a single flange with an inwardly facing structural element.

The modified design does not have flanges with hinge-forming trunnions as required by claim 1(a); instead there are protruding extensions on each end of the covering portion's cylindrical barrel that insert into recesses in the housing body. In addition to differences in composition, the Court notes differences between the lid operating mechanism of the '085 Patent and the modified design. The modified design does not have the damping means arranged within one of the cylindrical bores of the lid structure. Rather, the damping means is primarily located within the housing.

Claim 1 requires the lid structure to cover the display panel in the closed position. Because there are two closing layers in the double flipper, the lid structure does not cover the display panel in the closed position, nor does it expose the display panel when opened. Instead, when the lid structure covering the display is opened, the second portion of the housing covers the display panel (this second portion of the housing then opens). Overall, the double flipper opens in a different configuration than that described by the '085 Patent. Moreover, the double flipper's components are similar to the modified calculator and non-infringing for the same reasons noted above.

Id. at 10-11.

In its opinion denying Sun Coast's motion for attorney fees, the district court found that the case was not "exceptional" because Sun Coast had not established by "convincing clarity the egregiousness of CCL's counsel's conduct or a bad faith and vexatious multiplication of proceedings." *Attorney Fees Order*, slip op at 2. Additionally, the court denied sanctions in the form of attorney fees under 28

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U.S.C. § 927 for essentially the same reasons, finding that “CCL’s counsel did not multiply proceedings unreasonably and vexatiously” *Id.* at 2-3. Lastly, the court declined to utilize its inherent powers to sanction CCL or its counsel because they did not act “in bad faith, vexatiously, wantonly, or for oppressive reasons [even though,] the court may not have appreciated the zeal or decorum with which CCL and its counsel litigated this matter” *Id.* at 3.

*4 CCL appeals the grant of summary judgment of noninfringement. Sun Coast cross-appeals the denial of attorney fees. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II DISCUSSION

A. Standard of Review

We review a district court’s grant of summary judgment de novo, reapplying *11 the standard applicable at the district court. *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1301 (Fed.Cir.1999). Summary judgment is appropriate when it has been shown “that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law” Fed.R.Civ.P. 56(c); *Contract Mgmt., Inc. v. Rumsfeld*, 434 F.3d 1145, 1146 (9th Cir.2006).

Determining infringement generally requires two steps. “First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process.” *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1576 (Fed.Cir.1993).

Claim construction is an issue of law that we review de novo. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed.Cir.1998) (en banc); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir.1995) (en banc), *aff’d*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). “When interpreting claims, we inquire into how a person of ordinary skill in the art would have understood claim terms at the time of the invention.” *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1372-73 (Fed.Cir.2005) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed.Cir.2005) (en banc)). “The

inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation.” *Phillips*, 415 F.3d at 1313. “Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification” *Id.*

Infringement, whether literal or under the doctrine of equivalents, is a question of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed.Cir.1998). The proper inquiry is whether the evidence is such that a reasonable jury could return a verdict for the non-movant. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). We must draw all justifiable inferences in favor of the non-movant. *Id.*

A court may award attorney fees to a party in “exceptional” cases pursuant to 35 U.S.C. § 285. A trial court undertakes a two-step inquiry to adjudicate a request for attorney fees: the court examines whether there is clear and convincing evidence that the case is exceptional; and if so, whether an award of attorney fees to the prevailing party is warranted. *Evident Corp. v. Church & Dwight Co., Inc.*, 399 F.3d 1310, 1315 (Fed.Cir.2005) (citing *Cybor*, 138 F.3d at 1460; *J.P. Stevens Co. v. Lex Tex Ltd.*, 822 F.2d 1047, 1050 (Fed.Cir.1987)). Whether a case is exceptional depends on findings of fact by the trial court, which we review for clear error. *Rolls-Royce, Ltd. v. GTE Valen on Corp.*, 800 F.2d 1101, 1111 (Fed.Cir.1986). Pursuant to 35 U.S.C. § 285, the decision to award attorney fees is committed to the discretion of the trial court, which we review for an abuse of discretion. *Evident Corp.*, 399 F.3d at 1315 (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed.Cir.1995)).

B. Analysis

I. Claim Construction

a. “trunnions”

**5[1] In construing the term “trunnions” in claim 1 of the ‘085 patent, the district court noted that the parties did not dispute the single word “trunnion,” but rather the context in which the term is used in the claim. The district court, relying on a dictionary

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definition of trunnions, construed the term to mean "pins or pivots *12 usually mounted on bearings for rotating or tilting something" *Markman Opinion*, slip op at 13. Reading the claim term in the context of the surrounding claim language, "hinge-forming trunnions being formed on inwardly facing surfaces of said flanges[.]" the court found that because the claim requires that the trunnions be formed "on" the inwardly facing surfaces of the flanges, they must project from the inwardly facing surface of the flanges. The court recognized that several portions of the '085 patent specification, including the "Summary of the Invention" and "Detailed Description of a Preferred Embodiment" sections, refer to the trunnions "as types of projections[.]" thereby reinforcing the conclusion that some type of projection is required. In reaching its construction, the court rejected CCL's argument that the term "trunnion" as used in the claim could be construed to cover a pure recess or indentation in the surface of the flange because "[w]hile such recess might be a trunnion, it would be one that is formed in, not on, the inwardly facing surface of the flanges" *Id.* Therefore, the court concluded that "the trunnions identified in the claim language are ones that project from the inwardly facing surface of the flanges" *Id.*

On appeal, CCL argues that the district court erred in construing "trunnions" as being limited to "projecting" trunnions. Specifically, CCL contends that the court grafted a limitation from the preferred embodiment onto the trunnion term; that limitation being some type of projection. CCL asserts that the claim language "on inwardly facing surfaces of said flanges," "simply defines the location of the trunnions 'on the flange'." Alternatively, CCL asserts that if the trunnion term were limited to a projection, there is no reason to further limit it to a structure that does not contain a recess, especially when such a construction would exclude the preferred embodiment.

Sun Coast, on the other hand, argues that the district court correctly construed the term "trunnion" as requiring some type of projection, and thus excluding a pure recess, based on the context of the term in the claim itself and the disclosures in the specification. First, Sun Coast echoes the district court's conclusion that the claim language states that the trunnions are formed "on" the surfaces of the flanges and not "in" the surfaces, and therefore the claim language itself

does not support CCL's argument that a trunnion could be a pure recess. Second, Sun Coast asserts that "[a] trunnion cannot be a [pure] recess because the specification describes a recess as part of the projecting trunnion." (Pls.-Cross Appellants' Br 48.) Finally, Sun Coast argues that as correctly construed, the projecting "trunnions" cannot contain a recess and if such a construction excludes the preferred embodiment it is because of poor claim drafting.

**6 "[T]he words of a claim 'are generally given their ordinary and customary meaning.'" *Phillips*, 415 F.3d at 1312 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). That ordinary meaning "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. "[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms." *Id.* at 1314. In particular, "the context in which a term is used in the asserted claim" and the "[o]ther claims of the patent in question" are useful for understanding the ordinary meaning. *Id.* As we have stated on numerous occasions, the claims "must be read in view of the specification, of which they are a part." *Markman*, 52 F.3d at 979. "[T]he specification 'is always *13 highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582).

We can discern no error in the district court's *Markman* construction of the term "trunnions." First, the claim language itself states "hinge-forming trunnions being formed on inwardly facing surfaces of said flanges[.]" '085 patent, col 7, ll 9-10 (emphasis added). We do not believe that the term "on" was merely a reference to the location of the trunnions, but rather a limitation on the types of trunnions which were being claimed. Thus, we agree that the claim language itself does not support a construction of the term that would consist of a pure recess as such a trunnion would no longer be formed "on" the surface of the flanges, but rather "in" the surface. The claim language, however, supports a construction that the trunnions must be some type of projection, as that projection would aptly be considered "on" the surface of the flanges. Second, the specification consistently refers to trunnions as

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being some type of projection and the preferred embodiment is described as having "a short inwardly extending trunnion-like projection 28, 30[]" This is not, however, a limitation which is only associated with the preferred embodiment as argued by CCL. '085 patent, col 4, ll 12-13 The "Summary of Invention" section states that the "trunnions which project inwardly from upper ends of flanges extend from the side walls of the calculator housing, to the opposite open ends of the cylindrical bores and form hinge connections for the lid structure with the calculator housing" '085 patent, col. 2, ll 45-50 (emphasis added) Therefore, based on the context of the claim language and the description of the trunnions in the specification, we agree with the district court that the term trunnions be construed as "pins or pivots usually mounted on bearings for rotating or tilting something that project from the inwardly facing surface of the flanges" ^{FN1}

^{FN1}. This was essentially the district court's claim construction embodied in its *Markman* opinion, although we have compressed the court's statements into a one sentence construction See *Markman Opinion*, slip op at 13

additional limitation which prevents the trunnion from being some type of projection which contains a recess ^{FN2} First, the context of the claim language does not exclude a projection containing a recess because such a trunnion would still be "on" the surface of the flanges Second, such a projection is specifically disclosed as part of the preferred embodiment Figure 9 of the '085 patent illustrates that, "[o]ne of the projections 28 is larger in diameter, and projection 28 contains a circular recess 32 including a horizontal rib 34 extending radially from the bottom of the recess 32" '085 patent, col 4, ll 13-17 (emphasis added)

^{FN2}. In the district court's summary judgment order, it appears that the court may have limited the term "trunnions" to solid projections (i.e., those that do not contain a recess) While the term as construed in the *Markman* opinion was limited to some type of projection, thereby excluding a pure recess, there is no subsequent limitation on the projection such that it could not itself include a recess

*14 FIG 9

**7 While we affirm the district court's *Markman* construction of "trunnions," we note that there is no

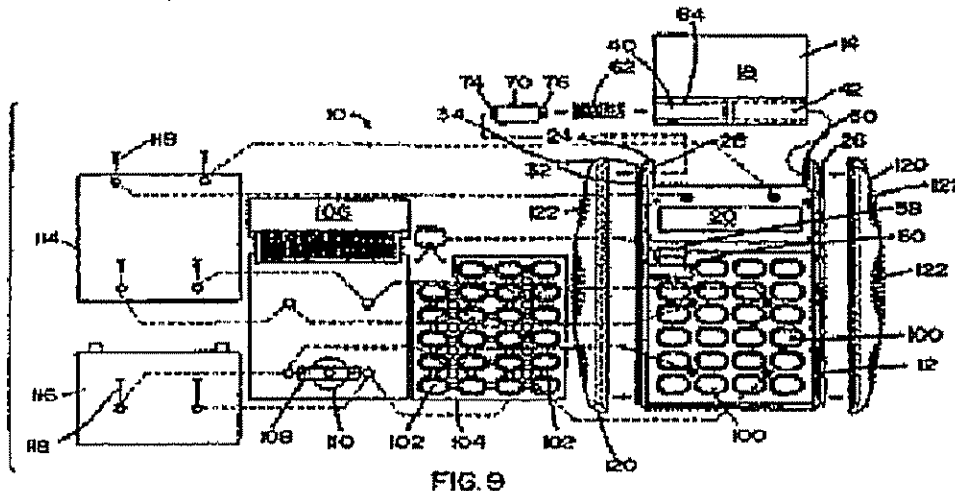


FIG. 9

As shown in Figure 9, projection 28 is a trunnion which contains a recess Thus, a construction of the term "trunnion" that excludes a projection containing a recess would exclude projection 28 as shown in

Figure 9 Third, as Sun Coast admits, "the specification describes a recess as part of the projecting trunnion" (Pls.-Cross Appellants' Br 48) Therefore, there is no apparent reason to limit the term in a way that would exclude the preferred

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embodiment. Accordingly, based on the claim language and the disclosures in the specification, the term *trunnion*, although required to contain a projection, is broad enough to include a projection with a recess, an example of which is shown in Figure 9 of the preferred embodiment, and to the extent that the district court may have applied a more limited construction of the term in its summary judgment order, that application was erroneous.

b “damping means”

[2] Because we find that the district court erred in its infringement analysis of whether the accused modified design calculator practices the “damping means arranged within at least one said cylindrical bore” limitation of claim 1, *see infra* Part II B 2 b, it becomes necessary for us to address the court's claim construction of the term “damping means.” The district court correctly determined that “damping means” is a means-plus-function claim limitation. The district court erred, however, in identifying the function of the “damping means,” as merely “restrain[ing], in a controlled manner, the force of the helical spring when it is released.” *Markman Opinion*, slip op. at 15. The language of claim 1, “biasing said lid toward a rearwardly pivoted position, and effectuating a controlled pivotal motion of said lid structure . . .” makes clear that there are two functions of the “damping means”: (1) biasing the lid toward a rearwardly pivoted position and (2) effectuating a controlled pivotal motion of the lid. Having misconstrued the functions of the “damping means,” the district court also erred in determining which structures are identified in the specification as performing those functions. In two places, the specification discusses the structures involved with both biasing and effectuating a controlled pivotal motion of the lid structure. In column 4, the specification states,

*8 [a]s shown in FIGS 8(a) through (c), a damping drum 70 in conjunction with the helical coil spring 62 form *15 the lid mechanism 16 for effectuating the pivoting movement of the lid structure 14 relative to the housing 12. The assembly of the components of the lid mechanism 16 into the blind bore 40 so as to effectively facilitate the controlled damped pivoting of the lid structure comprises inserting the helical coil spring 62 into the blind bore 40.

'085 patent, col 4, ll 48-60 (emphases added). This portion of the specification makes clear that the damping drum 70 and the helical coil spring 62 bias and effectuate the pivoting movement of the lid structure and that these structures are the components of the lid mechanism which facilitate the controlled damped pivoting of the lid structure. In addition, the specification states that *the rate of movement or speed in the rearward pivoting of the lid structure 14 upon the release thereof is controlled by means of the damping drum 70 and the damping grease 84 arranged thereabout in contact with the inner surface of the blind bore 40 which, in essence, forms a damping cylinder*.

Id. at col 5, ll 44-49 (emphases added). This portion of the specification makes clear that the damping drum 70 and the damping grease 84 control the rate of movement or speed of the lid structure as it pivots rearward. Thus, reading these two portions of the specification together compels the conclusion that the corresponding structures identified in the specification for performing the functions of biasing the lid toward a rearwardly pivoted position and effectuating a controlled pivotal motion of the lid are the damping drum 70, the helical coil spring 62, and the damping grease 84. ^{FN3}

^{FN3}. We note that the conclusion that the structure includes the helical coil spring 62 does not violate the doctrine of claim differentiation, even though the district court determined otherwise. Claim 3 explicitly claims “[a] calculator wherein said damping means comprises a helical coil spring and a damping drum.” ’085 patent, col 7, ll 33-36. Thus, claim 3 explicitly states that the “damping means” includes a helical coil spring and a damping drum. If including the helical coil spring as part of the structure for the “damping means” limitation in claim 1 violates the doctrine of claim differentiation, then including the damping drum as part of that structure would do so as well because it is also explicitly referenced in claim 3. Regardless, including the spring and drum as part of the “damping means” structure does not violate the doctrine of claim differentiation because claim 3 includes several limitations not present in claim 1.

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pertaining to the orientation and location of the spring and drum in relation to the blind bore and each other

2 Literal Infringement

Because the district court's summary judgment order separately discusses each of the accused calculator designs, we have followed suit and continue to discuss each design separately

a Original Design

In its summary judgment opinion, the district court concluded that the original design calculators were missing at least two limitations of claim 1. First, the court found that "the calculators do not have projections on the inner surface of both sides of the housing about which the lid rotates." *Summary Judgment Order*, slip op. at 10. Second, in noting that the calculators do not have projections, the court also stated that they "do not have flanges with hinge-forming trunnions (pins or pivots) that are distinct components." *Id.* Third, the court concluded by observing that the calculators "only appear to have a single flange with an inwardly facing structural element." *Id.*

*16 Literal infringement requires that each and every limitation set forth in a claim appear in an accused product. *Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l. Inc.*, 389 F.3d 1370, 1378 (Fed.Cir.2004) (citing *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 796 (Fed.Cir.1990)). With regard to the district court's first finding, it is not entirely clear to us whether the court's conclusion that the original design calculators lacked projections on the inner surface of both sides of the housing was based on the incorrect understanding that a trunnion could not consist of a projection containing a recess. Because it appears that the district court's finding may have been based on that incorrect understanding, we are unable to discern on this record whether this issue (i.e., the factual determination of whether the original design calculators include "trunnions" as that term has been construed by this panel) is amenable to summary judgment or whether genuine issues of material fact remain as to whether the original design calculators practice this claim limitation.

**9 Second, the parties apparently agree that there is

no prohibition on the trunnions and flanges being formed as one integral piece (See Pls.-Cross Appellants' Br. 52.) It appears that the district court's comment about trunnions and flanges being "distinct components" was not made in an attempt to further construe the claim terms, but rather in response to submissions by CCL which purported to label the same structure as both a flange and a trunnion. While there is no question that the trunnions and flanges must be distinctly identifiable, it is also clear that they are related. For example, the trunnions are identified in the specification as being parts of the flanges, "the housing 12 includes a pair of upwardly extending flange elements 24, 26 at opposite sides thereof, each of which includes a short inwardly extending trunnion-like projection 28, 30." '085 patent, col. 4, ll. 9-13. Thus, if the district court meant this statement as a comment in response to CCL's submissions, namely that the trunnions and flanges be distinctly identifiable, then we agree. If, on the other hand, the district court meant this statement to be another limitation of the claim rather than a comment on CCL's submissions, we find that there is a genuine issue of material fact as to whether the flanges and trunnions in the original design are distinctly identifiable so that summary judgment based on this reason alone is not appropriate. Accordingly, at least some additional clarification is required.

Third, the court also concluded that the original design "appears" to contain only a single flange with an inwardly facing structural element or projection, whereas the claims require "a pair of flanges[,] each of which containing a trunnion formed on the inwardly facing surface." See, e.g., '085 patent, col. 7, ll. 7-10. Even if we were to accept the district court's statement as a definitive finding that the original design contains only a single flange with a trunnion, we must vacate the district court's conclusion as it is unclear whether the court applied an erroneous construction of the "trunnions" term because the court has failed to set forth what, if any, structure the original design calculators have on the other side of the housing. Thus, we cannot determine in the first instance if whatever structure there may be qualifies as a trunnion.

Notably, we express no opinion with respect to whether summary judgment may ultimately be appropriate in light of the clarified claim construction.

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rulings and their subsequent effect on the summary judgment order of the district court. We leave that determination to the district court in the first instance after considering *17 any subsequent summary judgment briefing or argument by the parties that the court may deem necessary. If genuine issues of material fact remain as to whether the original design calculators possess each and every limitation of the claims, then the appropriate conclusion is to deny summary judgment and let the facts be decided at trial.

b. Modified Design

*10 In its summary judgment opinion, the district court concluded that the modified design calculators are missing two of the limitations of claim 1. First, the court found that "[t]he modified design does not have flanges with hinge-forming trunnions as required by claim 1(a); instead there are protruding extensions on each end of the covering portion's cylindrical barrel that insert into recesses in the housing body." *Summary Judgment Order*, slip op. at 11. Second, the court found that the calculators do "not have the damping means arranged within one of the cylindrical bores of the lid structure. Rather, the damping means is primarily located within the housing." *Id.*

First, because the district court's conclusion with respect to the trunnion limitation may be affected by our clarified claim construction, we vacate the court's finding of summary judgment of noninfringement with respect to this term. Second, the district court found that the "damping means" in the modified design calculators was not arranged within one of the cylindrical bores of the lid structure. Thus, as the parties have argued, the court was apparently focused on the term "within." The difficulty we have in reviewing the district court's finding regarding this term is not necessarily the finding itself, but rather the court's analysis which led to its finding. This is so because the full term in context is "a lid operating mechanism including *damping means arranged within at least one said cylindrical bore*." *085 *patent*, col. 7, ll. 19-20 (emphasis added). As previously discussed, the "damping means" limitation is a 35 U.S.C. § 112, ¶ 6 limitation, whose functions are to bias the lid toward a rearwardly pivoted position and effectuate a controlled pivotal motion of the lid. See *supra* Part II B 1 b.

Additionally, as we have clarified, the corresponding structures are the damping drum 70, the helical coil spring 62, and the damping grease 84. *Id.*

"Literal infringement of a § 112, ¶ 6 limitation requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Frank's Casing*, 389 F.3d at 1378 (quoting *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1267 (Fed.Cir.1999)). To determine whether a § 112, ¶ 6 limitation is literally infringed, "the court must compare the accused structure with the disclosed structure, and must find equivalent structure as well as identity of claimed function for the structure." *Id.* (emphasis altered) (citation omitted). Although we recognize that the district court was not purporting to find that the modified design calculators lacked the "damping means" itself, the district court did not identify which structure(s) of the modified design calculators, if any, performs the claimed function of the "damping means." It is therefore impossible, on the record before us, to determine whether that yet identified structure is "arranged within at least one said cylindrical bore" as required by the claim or whether the district court correctly held on summary judgment that no genuine issue of material fact exists as to whether the modified design calculators satisfy this claim limitation.

*18*11 We further note that what appears to be relevant to this inquiry is whether the structure, yet to be identified in the modified design calculators, performs the biasing and effectuating a controlled pivotal motion functions "within at least one said cylindrical bore." Thus, if the relevant structure in the accused calculators is partially arranged within the bore, the appropriate inquiry seems to be whether that portion arranged within the bore is involved in performing the identified functions (i.e., biasing the lid toward a rearwardly pivoted position and effectuating a controlled pivotal motion of the lid). Accordingly, the court's finding of summary judgment of noninfringement with respect to the modified design calculators must be vacated.

Again, we express no opinion with respect to whether summary judgment may ultimately be appropriate in light of the clarified claim construction rulings and the court's conclusions with respect to the § 112, ¶ 6

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issue discussed above. We leave that determination to the district court in the first instance after considering any subsequent summary judgment briefing or argument by the parties that the court may deem necessary. If genuine issues of material fact remain as to whether the modified design calculators possess each and every limitation of the claims, then the appropriate conclusion is to deny summary judgment and let the facts be decided at trial.

c Double Flipper

[3] In its summary judgment opinion, the district court concluded that the double flipper was noninfringing for the same reasons it found that the modified design calculators were noninfringing. Additionally, the court found that [b]ecause there are two closing layers in the double flipper, the lid structure does not cover the display panel in the closed position, nor does it expose the display panel when opened. Instead, when the lid structure covering the display is opened, the second portion of the housing covers the display panel (this second portion of the housing then opens).

Summary Judgment Order, slip op. at 11.

On appeal, CCL argues that the district court impermissibly construed the claim term to require that the lid “directly” cover and alternatively, “directly” expose the display panel. CCL asserts that the presence of an intervening structure does not affect the covering and exposing functions of the lid.

We disagree. The claim language requires that the lid pivot “between the closed position thereof covering said display panel and the rearwardly pivoted position exposing said display panel and forming a stand for supporting said calculator in a tilted position on a horizontal surface.” 085 patent, col. 7, ll. 22-26 (emphasis added). Regardless of whether the lid in the double flipper covers the display panel in the closed position, the district court correctly concluded that when the lid structure opens (i.e., moves toward the rearwardly pivoted position), the display panel is not exposed because a second portion of the housing still covers the display. This finding, that the double flipper lacks a lid structure which exposes the display panel in the rearwardly pivoted position, permits an affirmance of summary judgment of non-infringement because each and every

limitation of the claim (i.e., the covering and exposing limitations) does not appear in the double-flipper. *See Frank's Casing*, 389 F.3d at 1378.

3 Infringement Under the Doctrine of Equivalents

****12[4]** While the district court's examination of the accused calculators and the '19 court's findings of infringement were in the context of literal infringement, the court also found that CCL failed to produce evidence of the equivalency of Sun Coast's products and the limitations of claim 1. [such that] [t]here is no question of fact here as there has been no evidence presented to the Court of any infringement by an equivalent to the cited claim elements on which a reasonable jury could base a finding of equivalence.

Summary Judgment Order, slip op. at 8 n. 5. The court had no reason to formulate its own possible theories of infringement under the doctrine of equivalents when CCL had failed to offer any evidence supporting such a finding. Sun Coast clearly asserted that CCL failed to offer any evidence on infringement under the doctrine of equivalents in its motion for partial summary judgment. Thus, the issue was squarely raised before CCL submitted its opposition brief. Accordingly, there was no obligation for the district court to provide CCL a further opportunity to **supplement** the record when it failed to present evidence of infringement under the doctrine of equivalents in its brief in opposition to Sun Coast's summary judgment motion. Further, the district court clarified that it “did not rely on either [the Ram or Bhavnani] declarations in making its findings[.]” contrary to CCL's assertion that the court improperly relied upon statements made in declarations attached to Sun Coast's reply brief. *Summary Judgment Order*, slip op. at 9 n. 6. Therefore, there was no obligation for the court to consider evidence (e.g., Chan's declaration) that CCL only first presented in its response to the court's minute order. As such, we do not disturb the court's findings with respect to infringement under the doctrine of equivalents.

4 Cross-Appeal

Sun Coast's cross-appeal challenges the district court's denial of attorney fees. Specifically, Sun Coast asserts that the district court committed clear

179 Fed Appx 6
 179 Fed Appx 6, 2006 WL 1044244 (C A Fed (Cal))
 (Cite as: 179 Fed.Appx. 6)

Page 12

error by not finding that this case was "exceptional" under 35 U.S.C. § 285; and abused its discretion by (1) refusing to award fees to Sun Coast under § 285, (2) alternatively not awarding fees under 28 U.S.C. § 1927, and (3) alternatively not awarding fees under its inherent powers. CCL asserts in response that the district court's finding that this case was not exceptional is not clearly erroneous, and that Sun Coast has failed to show that the court abused its discretion in failing to award attorney fees.

[5] We detect no clear error or abuse of discretion in the district court's denial of Sun Coast's motion for attorney fees. First, under 35 U.S.C. § 285, the court found that Sun Coast failed to establish by clear and convincing evidence actual wrongful intent or gross negligence by CCL. Although the district court acknowledged that CCL committed numerous violations of the local rules, and an unjustified number of ex parte applications, its conduct did not rise to the level of gross negligence or bad faith and vexatious litigation. "Taken in its totality, the record does not demonstrate with convincing clarity the egregiousness of CCL's counsel's conduct or a bad faith and vexatious multiplication of proceedings." *Attorney Fees Order*, slip op at 2. Second, the court similarly rejected Sun Coast's argument for fees under 28 U.S.C. § 1927 because the court found that CCL's counsel had not multiplied the proceedings unreasonably and vexatiously, and found that any protracted proceedings were equally attributable to Sun Coast's failure to identify all the calculators at issue in its motion for summary judgment. Lastly, the court rejected Sun Coast's argument for fees under 28 U.S.C. § 1927 because it found that the conduct of CCL and its counsel was not sufficiently egregious to warrant sanctions.

**13 The district court judge is in the best position, after presiding over the preparation and trial of the case, to "weigh the relevant considerations, such as the closeness of the case, the tactics of counsel, the flagrant or good faith character of the parties' conduct, and any other factors contributing to imposition of punitive sanctions or to fair allocation of the burdens of litigation." *Frank's Casing*, 389 F.3d at 1379 (citations omitted); *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1380-81 (Fed.Cir.2005). The court fully considered Sun Coast's arguments but found that CCL and its counsel's conduct was not so egregious as to warrant

an award of attorney fees. We can discern no clear error in the district court's factual findings, nor any abuse of discretion in the court's ultimate denial of attorney fees.

III CONCLUSION

Because we have clarified the construction of "trunnions" and "damping means", and several issues remain to be addressed by the district court, we remand for the district court to determine whether Sun Coast's original and modified designs literally infringe the asserted claims of the '085 patent. These clarifications, however, do not affect the district court's ultimate conclusion with respect to Sun Coast's Calc-0050 model because the court's decision relied upon the lack of the "covering" and "exposing" limitations, which we have not altered in such a way to create genuine issues of material fact with respect to whether the Calc-0050 infringes claim 1 of the '085 patent. Accordingly, we vacate the summary judgment findings with respect to literal infringement of the original and modified designs, affirm both the summary judgment findings of noninfringement with respect to literal infringement of the Calc-0050 model and noninfringement under the doctrine of equivalents of all calculator models at issue, affirm the district court's denial of attorney fees, and remand for further proceedings consistent with this opinion.

Each party shall bear its own costs.

C A Fed (Cal),2006
 Sun Coast Merchandise Corp v. CCL Products Enterprises, Inc
 179 Fed Appx. 6, 2006 WL 1044244 (C A Fed (Cal))

END OF DOCUMENT

EXHIBIT O

EXHIBIT O
REDACTED
IN ITS ENTIRETY

EXHIBIT P

April 18, 1967

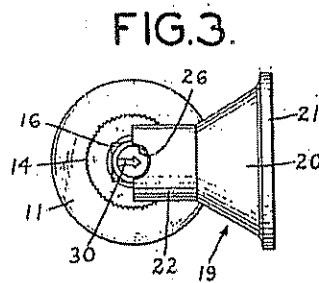
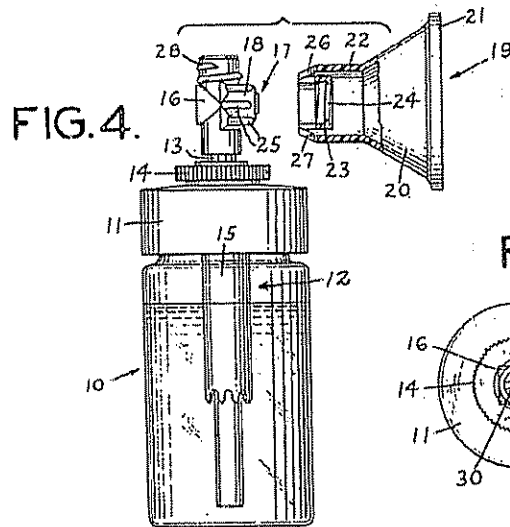
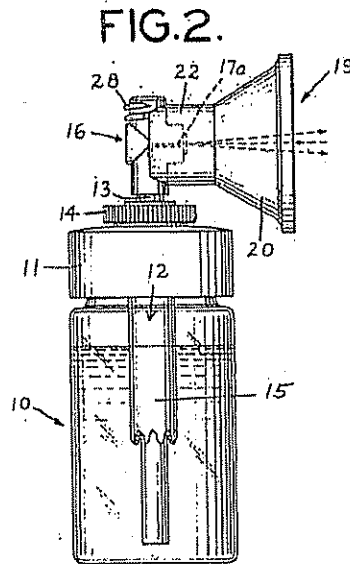
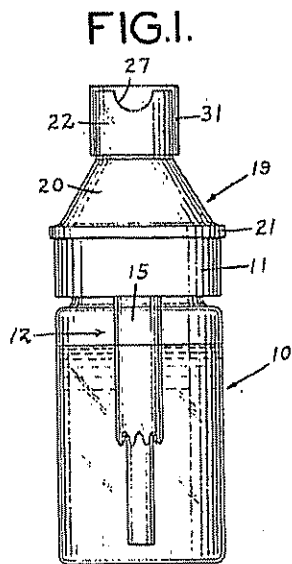
A. CARROLL

3,314,426

EYECUP AND SPRAY DISPENSER

Filed May 20, 1964

2 Sheets-Sheet 1



INVENTOR
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Anthony F. Sinner, Jr.

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April 18, 1967

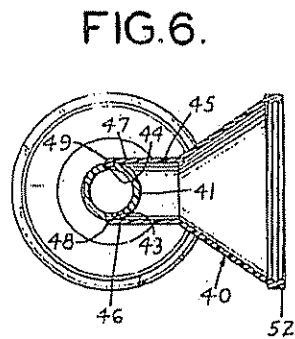
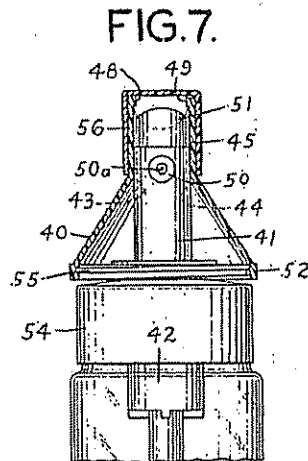
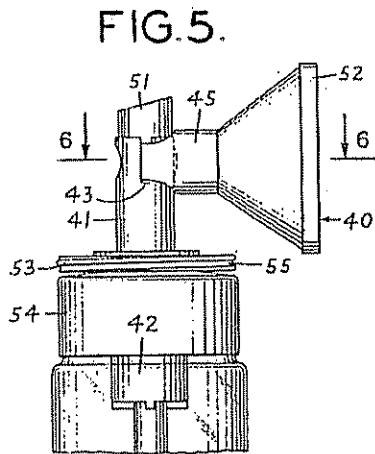
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3,314,426

EYECUP AND SPRAY DISPENSER

Filed May 20, 1964

2 Sheets-Sheet 2



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United States Patent Office

3,314,426

Patented Apr. 18, 1967

1

3,314,426

EYECUP AND SPRAY DISPENSER

Albert Carroll, Hartsdale, N.Y., assignor to Lever Brothers Company, New York, N.Y., a corporation of Maine

Filed May 20, 1964, Ser. No. 368,844

4 Claims. (Cl. 128-173)

ABSTRACT OF THE DISCLOSURE

This invention relates to a combined eyecup and spray dispenser having a plunger actuator for discharging a medicament through a laterally directed nozzle, the eyecup serving as a cover for the plunger and nozzle and adapted to be mounted on the nozzle to form an eyecup and shield and providing an illuminated target for attracting the eye so that medicament discharged from this nozzle can be directed into the center of the eye without involuntary blinking of the eye.

This invention relates to medication apparatus and relates particularly to apparatus for applying a medicament to the eyes, for lavage of the eyes and for treating eye diseases, infections, irritations, strain and the like.

The most common device for applying a medicament to the human eye is an eyecup formed of glass, plastic, metal or the like. While such eyecups have been used satisfactorily for the treatment of eyes, they are not without disadvantages. For example, in the hands of an unskilled user, the medicament frequently leaks or is spilled from the eyecup as it is applied to the eye. Moreover, the liquid in the eyecup is in a more or less quiescent state which renders it somewhat ineffective for removal of foreign particles or bodies from the eye. Because of these deficiencies of the ordinary eyecup, it has been proposed, heretofore, to provide eyecups with means for spraying a liquid into the eye of the user. For example, the container associated with the eyecup may be a squeeze bottle or provided with a syringe bulb, a pump or the like for squirting the medicament into the eye. These devices are not very satisfactory for the reason that a stream of the medicament is discharged with considerable force and volume into the eye. While in theory, the use of such a forceful stream will dislodge a foreign particle from the eye, in actual practice, the stream or jet causes the user to blink, with the result that the medicament may not reach the eye to exert its full washing effect.

Moreover, inasmuch as a relatively large volume of medicament is discharged into the eye, the eyecup must be applied tightly to the area around the eye to prevent leakage and careful handling is required to avoid spillage after use. Leakage can occur also due to inadvertent squeezing of the container or other actuating device during handling, shipping and the like.

The prior devices also are somewhat unwieldy for the eyecup usually extends outwardly from the container making its use, packaging and handling difficult.

Contamination of the prior dispensing eyecups by dust can occur for the reason that their inner surfaces are unprotected when not in use.

In accordance with the present invention, the difficulties and disadvantages of the prior devices are overcome by providing a spray dispenser for supplying a medicament to the eye in the form of a finely divided spray or mist and in a relatively small but adequate, metered amount. The dispenser has a shield to be applied over the eye to confine the spray to the eye area, the shield being removable and storable in a protective relation to the actuator by means of which the medicament is dispensed and with the inner surface of the eye shield protected from contamination.

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More particularly, the new dispensing device includes a container for a medicament and a device for discharging the medicament from the container including an actuating member which extends through the top or cover of the container and is provided with a laterally facing orifice of very small diameter, e.g. about 0.01 of an inch through which the medicament is discharged in the form of a spray or mist. The eye shield is constructed and arranged so that it can be attached to and detached from the nozzle and can also be stored on the upper end of the actuating member in such a position that the open end of the eye shield engages the cover for the container and covers and protects the orifice as well as the inner surface of the eye shield and retains the actuating member against movement so that it cannot be operated inadvertently to cause discharge of a medicament from the container.

In use, the eye shield is attached to the lateral extension containing the orifice or nozzle and can either be brought adjacent to the eye or lightly into contact with the area around the eye. Upon movement of the actuating member, a small amount of the medicament is discharged in the form of a fine mist or spray directly into the eye without such sharp impingement as to cause blinking of the eye. The amount of the medicament is small so that little if any of it escapes from the eye and accordingly, the device can be used with a minimum of difficulty, spillage or waste under almost any circumstances.

For a better understanding of the present invention, reference may be had to the accompanying drawing in which:

FIGURE 1 is a front elevational view of a typical medicament dispenser of the type embodying the present invention with the eye shield attached to the top of the container in condition for shipment, handling or storage;

FIGURE 2 is a side elevational view of the dispenser with the eye shield attached to the dispenser for application of the medicament to the eye;

FIGURE 3 is a plan view of the device shown in FIGURE 2;

FIGURE 4 is an exploded side elevational and partial sectional view of the dispenser;

FIGURE 5 is a side elevational view of a modified form of eyecup dispenser shown partly broken away;

FIGURE 6 is a view in section taken on line 6-6 of FIGURE 5; and

FIGURE 7 is a front elevational view of the dispenser of FIGURE 5 with the eye shield in stored position and with parts broken away to disclose details thereof.

The spray dispenser shown for purposes of illustration in FIGS. 1 to 4 of the drawings includes a container or bottle 10 formed of a glass, plastic or the like having a cover 11 which may be connected permanently or detachably to the upper end of the bottle 10. The cover 11 may be formed of plastic material or the like as desired. Mounted in the cover and extending downwardly into the container is a pump 12 of the plunger type such as that shown, for example, in U.S. Patent No. 2,362,080, dated November 7, 1944 and in my copending application Serial No. 260,216, filed February 21, 1963, now abandoned. The pump includes a piston (not shown) actuated by means of a plunger 13 which extends through the cover 11 and suitable check valves (not shown) which, upon downward movement of the plunger, cause a measured charge of the medicament to be discharged from the pump. Upon upward movement of the plunger 13 another charge of medicament is drawn into the pump. The pump plunger 13 is slidably received in a collar 14 which is mounted in the cover 11 of the container and carries the barrel or cylinder 15 of the pump which has its inlet near the bottom of the container.

3,314,426

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On the upper end of the plunger 13 is a head 16 forming an actuator, the upper end of which may be pressed by a finger to cause a metered amount of medicament to be discharged through a nozzle 17 having an orifice 17a and comprising a projection or boss 18 extending laterally from the head 16. The nozzle 17 is disposed midway between the upper and lower ends of the actuating head and is adapted to receive an eye shield 19 thereon.

As best shown in FIGURES 2, 3 and 4, the eye shield 19 includes a conical portion 20 having a rim 21 at its larger end adapted to engage the area around an eye and also, as shown in FIGURE 1, to engage the periphery of the cover 11 of the container.

A tubular sleeve portion 22 extends from the smaller diameter end of the conical portion 20 and has an internal annular surface 23 provided with internal threads 24 which are adapted to frictionally engage the ribs 25 on the extension 18. Diametrically spaced arcuate notches 26 and 27 are formed in the end of the sleeve 22 so that it fits snugly against the side of the actuator 16.

Inasmuch as the ribs 25 extend outwardly from the extension 18, spaces are present between them through which light is visible from the interior of the shield 20 when the latter is in engagement with the face around the eye. The light forms a target for attracting the eye to enable the medicament to be directed into the center of the eye when the actuating member 16 is pressed. The eye shield need not be pressed tightly around the eye for the amount of medicament discharged preferably is relatively small in volume and accordingly, the excess, if any, which would run out of the eye is negligible.

As shown in FIGURES 2 and 3, the upper or outer end of the actuator 16 is provided with threads 28 which are adapted to mate with the threads 24 to allow the eye shield 20 to be stored on the end of the container as shown in FIGURE 1. Thus, the eye shield 20 may be removed from the nozzle extension 18, inverted and then screwed on the upper end of the actuator 16 to engage the rim 21 with the cover 11. In this position, the eye shield covers the nozzle 17 and locks the actuator 16 against movement. Moreover, the inner surface of the eye shield 19 and the nozzle 17 are protected against dust and other contamination.

It will be understood that other types of threads 24 and 28 or other types of fastening means such as, for example, a bayonet slot connection may be used for attaching the eye shield to the upper end of the actuator 16 or to the cover 11 when the eye shield is not in use.

For convenience in attaching the eye shield to the actuator 16, the upper end of the actuator may have a suitable arrow 30 (FIG. 3) or other indicator pointing to the side where the eye shield should be attached.

As indicated above, the orifice in the nozzle 17 through which the medicament is discharged should be of such size as to cause the medicament to be discharged in a form of a mist or fog and to that end, the orifice preferably is between about 0.01 and 0.011 inch in diameter.

As a further protection for the dispenser, the upper end of the actuator and sleeve 22 of the eye shield may be covered by means of a cap 31 formed of plastic or the like which fits frictionally and detachably over the sleeve 22 of the eye shield.

By making the cover 11 removable from the container or the bottle 10, it is, of course, possible to refill the container as may be required or, the cover may be secured permanently to the container forming a "throw away" unit.

Other means for mounting the shield on the dispenser in condition for use and for storing the shield are equally suitable. As shown in FIGURE 5, the shield 40 is clipped to the actuating head 41 of the pump 42. Diametrically spaced grooves 43 and 44 are formed in the head and the cylindrical portion 45 of the shield 40 includes arms 46 and 47 having inwardly extending flanges 48 and 49

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which can be snapped into or slipped into the grooves 43 and 44. In this form of dispenser, the nozzle 50 and the orifice 50a therein are substantially flush with the surface of the plunger 41. Also, the upper end portion 51 of the plunger is of reduced diameter so that the shield can be stored by slipping it over the plunger and the rim 52 of the shield either frictionally engaged with the collar 53 on the cap 54 or threaded on the threads 55 on the collar, as illustrated. If desired, the collar 53 can be omitted and the parts proportioned so that the rim 52 of the shield either frictionally engages the upper end of the closure cap 54 or engages threads thereon. With either structure, the tubular portion 45 extends sufficiently above the upper end of the actuating head 41 that it cannot be depressed accidentally when the shield is stored on the container. Protection against contamination is afforded by means of a cap 56 slidably received on the tubular extension 45 as shown in FIGURE 7.

Dispensers of the type described above can be readily packed in cartons, boxes or the like and can be shipped without danger of loss of the contents and without danger of contamination of the eye shield or those parts with which the medicament comes in contact. Moreover, when made in small sizes, the dispenser can be carried in pocket, purse or the like without danger of leaking or becoming contaminated and thus is available for use at any time. Inasmuch as only small increments of the medicament are discharged for treating an eye, it is unnecessary to take any precautions in the use of the device and accordingly, it can be used whenever and wherever required.

Many other variations and modifications of the dispenser are possible and accordingly, the form of the invention described herein should be considered illustrative.

I claim:

1. A spray dispenser comprising a container for a medicament, a cover for said container, means mounted on said cover and extending into said container and having a plunger for discharging medicament from said container, an actuator on said plunger, a nozzle in said actuator for directing a spray of said medicament laterally from said actuator upon actuation of said plunger, an eye shield, a boss extending laterally from said actuator for detachably supporting said shield on said actuator with said shield extending laterally from said actuator substantially coaxial with said nozzle, a plurality of ribs and grooves on and extending longitudinally of said boss, first means in said shield frictionally engageable with said ribs and spacing said shield from said boss whereby said grooves between said boss and said shield admit light and second means on said shield for detachably connecting said shield to said container with said shield substantially coaxial with said plunger and covering said nozzle, said second means comprising threads on said actuator and on said shield for connecting said shield to said actuator, said shield having a rim engageable with said cover to prevent actuation of said plunger when said shield is connected to said actuator by said second means.

2. The dispenser set forth in claim 1 in which said shield comprises a hollow frusto-conical portion and a sleeve portion extending from the smaller diameter end of said frusto-conical portion, said threads being in said sleeve portion.

3. The eyecup dispensing means set forth in claim 1 in which said means for discharging medicament comprises a pump.

4. A spray dispenser for applying a medicament to the human eye and furnishing an illuminated target for attracting the eye to enable the medicament to be introduced into the center of the eye, comprising a container for a medicament, a cover for said container, means mounted on said cover extending into said container and below the level of said medicament for flow of said medicament therethrough and having a plunger for discharging said medicament from said container, an actuator

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on said plunger, a boss extending laterally from said actuator having an orifice therein for directing a spray of said medicament laterally from said actuator upon actuation of said plunger, an eye shield, means on said eye shield for detachably connecting said eye shield to said container with said eye shield substantially coaxial with said plunger and covering said boss, and spaced frictionally engageable means on said boss and said eye shield spacing portions of said eye shield from said boss to provide openings extending lengthwise of said boss for passage of light therethrough whereby light is visible from the interior of said eye shield through said openings between said boss when said eye shield is in engagement with the space around the eye.

6

References Cited by the Examiner

UNITED STATES PATENTS

2,826,194	3/1958	Golden	128—173
2,870,943	1/1959	Scoggin	222—538 X
2,985,382	5/1961	Coplan	239—288.5
3,169,525	2/1965	Bowen	128—272 X
3,200,817	8/1965	Brainard	128—173
3,209,751	10/1965	Wakeman	128—173
3,247,849	4/1966	Wise et al.	128—173

RICHARD A. GAUDET, *Primary Examiner.*W. E. KAMM, *Assistant Examiner.*

EXHIBIT Q

April 14, 1970

C. H. COSTELLO

3,506,001

EYE-SPRAYING DEVICE HAVING MIRROR

Filed Nov. 4, 1966

FIG. 1.

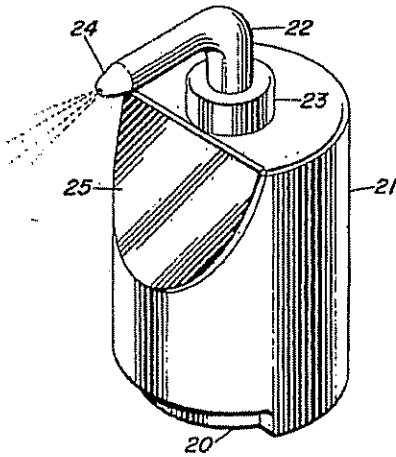
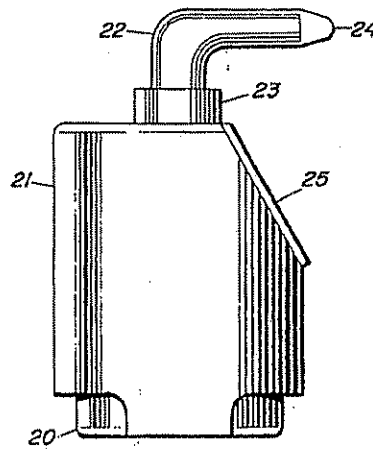


FIG. 2.



INVENTOR

Christopher H. Costello

United States Patent Office

3,506,001

Patented Apr. 14, 1970

1

3,506,001

EYE-SPRAYING DEVICE HAVING MIRROR

Christopher Hollet Costello, Summit, N.J., assignor to Colgate-Palmolive Company, New York, N.Y., a corporation of Delaware

Filed Nov. 4, 1966, Ser. No. 592,025
Int. Cl. A61m 11/00

U.S. Cl. 128—173

1 Claim

ABSTRACT OF THE DISCLOSURE

The device disclosed herein includes a container for medicated solutions to be administered to the eye, an outlet member associated with the upper portion of the container serving as a directional sprayer, and a mirror mounted and positioned on the device so that the image of the eye is reflected to the user of the device.

The present invention relates to administering medicated solutions to the eye and, more particularly, to spray devices for administering medicated solutions to the eye and provided with a mirror so placed on the spray device that the operator by seeing the reflected image of the operator's eye can direct a spray accurately into the eye which is reflected in the aforesaid mirror.

The conventional methods of administering medicated solutions to the eye are by the use of droppers and eye cups or baths. Since these come in direct contact with the eye, the opportunity for transfer of infection to the dropper or eye cup or to the medicated solution is considerable. The use of a fine spray by means of a nebulizer, squeeze bottle or aerosol devices has greatly reduced the risk of infection. However, considerable difficulty is experienced with these devices in accurately directing the medication into the eye.

The present invention provides for the attachment to the spray device of a small mirror so placed on the spray device that the operator by seeing the reflected image of the operator's eye to be treated can direct the spray accurately into the eye. The mirror also serves to focus light on to the eye. The mirror is positioned on the spray device so that the image of the eye to be treated is reflected and the spray of medicated solution is accurately directed simultaneously. By the use of the mirror on the spray device the spray can be directed into the eye before the reflex action called the wink, takes place.

While the mirror can be mounted on the spray device in any position which with or without movement or adjustment thereof provides a reflection of the eye to be treated which is seen by the operator's eye, it is preferred to mount the mirror on part of the spray device, as will be manifest from the drawings in which:

FIGURE 1 is a perspective of a container having a

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button controlling the discharge of the contents of the container mounted in the bottom thereof and having a mirror mounted on the side of the container below the discharge outlet of the dispensing nozzle; and

FIGURE 2 is a side view of the container illustrated in FIGURE 1.

A similar container 21 having a depressible button 20 in the bottom of container 21 is illustrated in FIGURES 1 and 2. As those skilled in the art know an aerosol cartridge containing the medicament is inserted in container 21 and the discharge thereof controlled by button 20. By pressure upwards on button 20 the contents of container 21 is discharged through tube 22 mounted in closure 23 and thence through nozzle 24. The container is fabricated from any suitable material, preferably relatively rigid plastic which is molded to provide at one side a plane surface having an angle of about 45 degrees downward with the surface of the top of the container. The mirror 25 is mounted on said plane surface and the closure 23, bearing the discharge tube 22, is mounted on the container with the nozzle in line with the vertical axis of the mirror 25.

What is claimed is:

1. A device for administering to an eye a burst of medicament-containing mist, said device comprising a substantially rigid container, a closure member mounted on the container, a discharge tube mounted in said closure, said discharge tube including a dispensing nozzle, and an aerosol means for propelling medicated solution through said discharge tube and out said dispensing nozzle, said container having an inclined plane surface centered on the vertical axis of the discharge tube and making an angle of about 45° downward from the top of the container and a mirror mounted on said inclined plane surface with said dispensing nozzle in line with the vertical axis of the mirror so that reflections of the eye and of the dispensing nozzle can be seen by the user of the device.

References Cited**UNITED STATES PATENTS**

1,855,653	4/1932	Strauss	128—249
2,736,316	2/1956	Stovall	128—233
2,382,771	8/1945	Bowers	128—233
3,200,817	8/1965	Brainard	128—173
3,314,426	4/1967	Carroll	128—173

RICHARD A. GAUDET, Primary Examiner

J. D. YASKO, Assistant Examiner

U.S. Cl. X R.

128—21; 222—106, 192

EXHIBIT R

US005588564A

United States Patent [19]**Hutson et al.**[11] **Patent Number:** **5,588,564**[45] **Date of Patent:** **Dec. 31, 1996**[54] **EYE SPRAY MIST DISPENSER**

[76] Inventors: **Clifford L. Hutson**, 4440 J Shadow Hills Cir., Santa Barbara, Calif. 93105;
Robert Demangus, 1715 N. Pacific Ave., Glendale, Calif. 91202-1108

[21] Appl. No.: **518,143**[22] Filed: **Aug. 21, 1995**[51] Int. Cl.⁶ **B67D 5/40**[52] U.S. Cl. **222/383.1; 222/523; 222/525; 604/301**[58] Field of Search **222/383.1, 523, 222/525, 526, 527; 604/289, 294, 295, 298, 300, 301, 302**[56] **References Cited****U.S. PATENT DOCUMENTS**

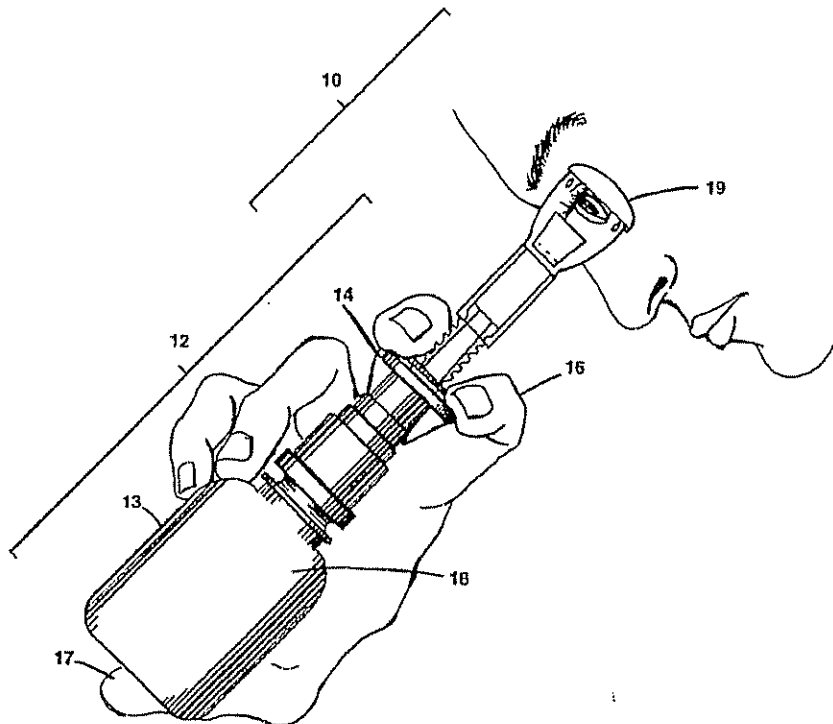
2,320,070	5/1943	Derham et al.	604/295
3,910,618	10/1975	Massenz	604/294 X
4,257,417	3/1981	Gibilisco	604/302
4,733,802	3/1988	Sheldon	604/302 X
4,792,334	12/1988	Py	604/301
5,030,214	7/1991	Spector	604/289 X
5,037,406	8/1991	Smith et al.	604/301
5,201,726	4/1993	Kirkham	604/294

Primary Examiner—Joseph Kaufman
Attorney, Agent, or Firm—Michael G. Petit

[57] **ABSTRACT**

A device including an eye cup portion affixed to one end of

an extendible tube portion, the other end of the tube portion is adapted for releasably attaching the tube portion to the nozzle of a spray-mist fluid dispenser. In combination, the device and mist dispenser are operable for controlling the delivery of a fluid to the eye. The device functions both as a mask to confine the distribution of the spray mist ejected from the nozzle upon the eye and as a jig operable for adjusting the distance between the mist dispenser nozzle and the eye cup portion of the device. In operation, with the device affixed to a spray mist dispenser nozzle and the tube portion unextended (nozzle closest to the eye), a dense mist is delivered to the cornea and surrounding eye tissues when mist is dispensed. When the tube portion is extended, the spray mist dispenser nozzle is further from the eye cup thereby reducing the density of the spray mist impinging on the eye. The tube portion of the device includes inner and outer concentric tubes and a conical containment chamber affixed to the outer tube and disposed within the eye cup portion of the device. The distance between the wide end of the eye cup and the nozzle engaging end of the tube portion is telescopically adjustable. The containment chamber may be removed from the device to permit the spray nozzle to be positioned nearer the eye. When the tube portion is unextended, the fluid spray mist impinges on the anterior surface of the eye with the greatest force and concentration. For a gentler, finer delivery of spray mist, the containment chamber is preferably employed and the distance between the dispenser's nozzle delivery orifice and the eye cup portion adjusted and set for comfort and accurate dosimetry.

5 Claims, 3 Drawing Sheets

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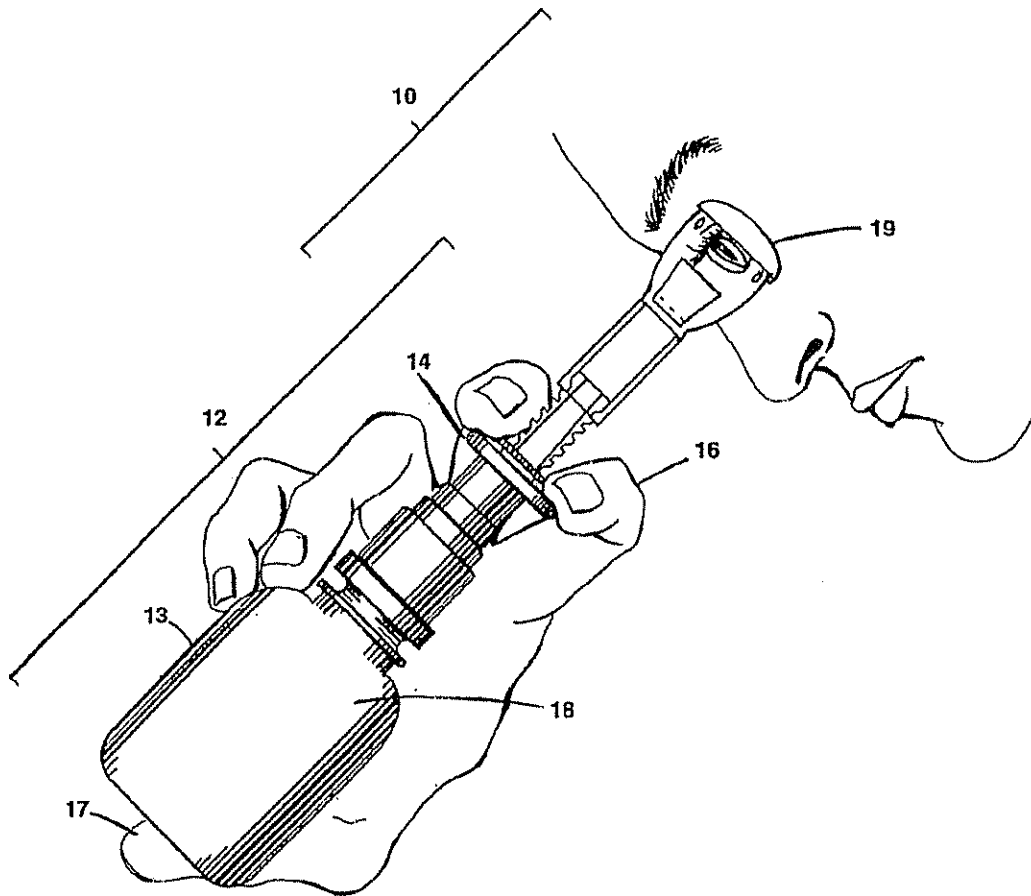


FIG. 1

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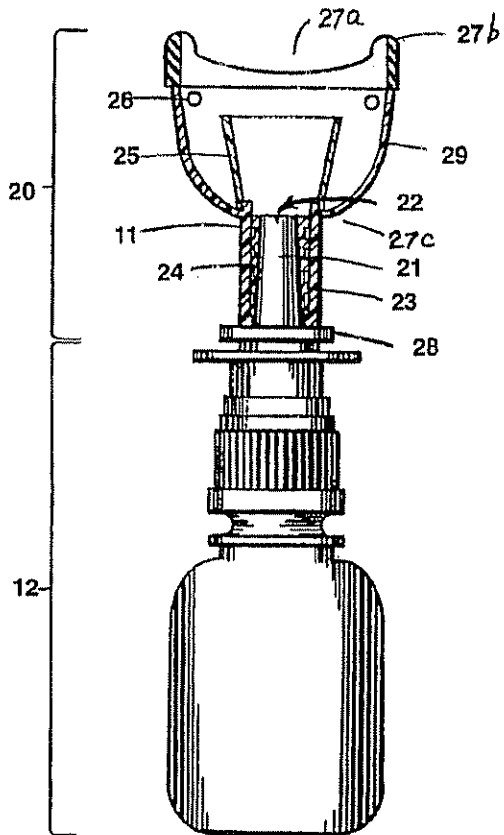


FIG. 2

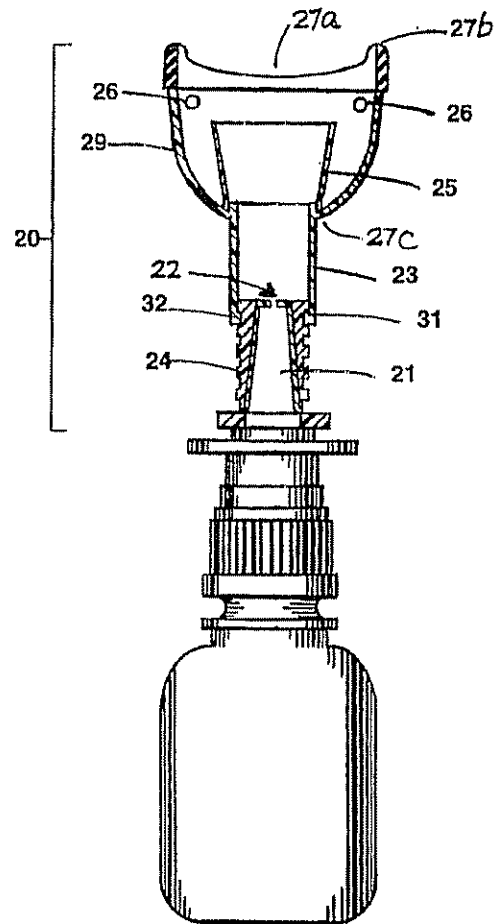


FIG. 3

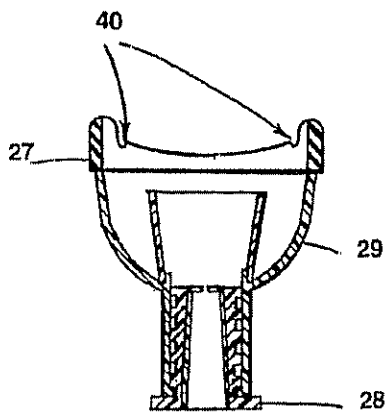


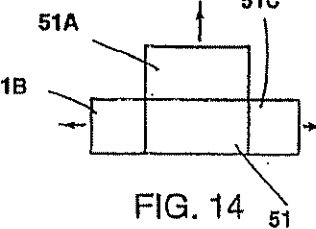
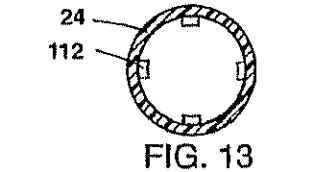
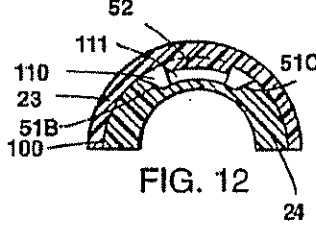
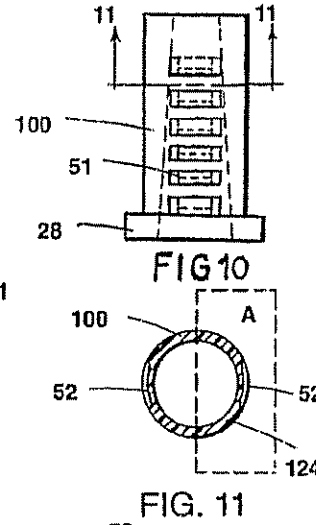
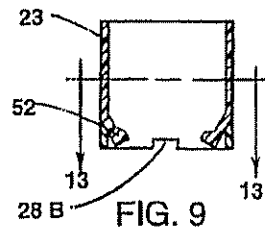
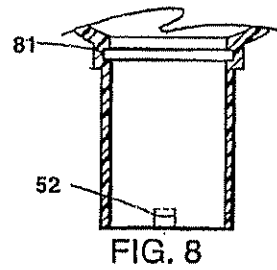
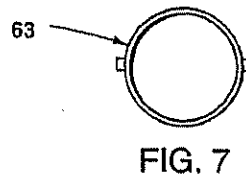
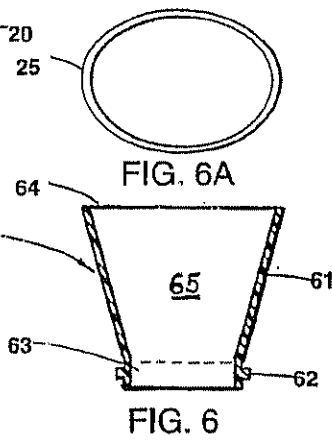
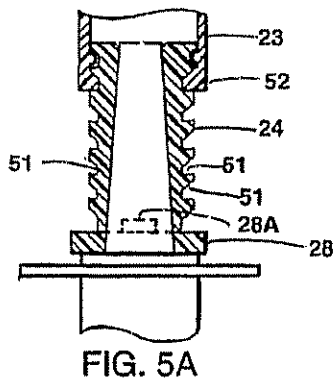
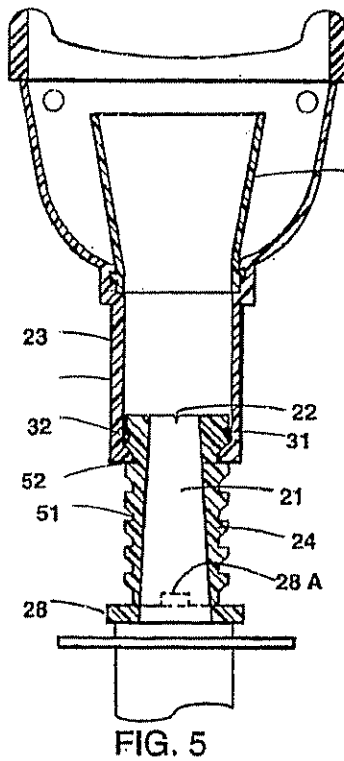
FIG. 4

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EYE SPRAY MIST DISPENSER**BACKGROUND OF THE INVENTION****1. Field of the Invention**

This invention relates to a device for topically administering a fluid to the eye and, more particularly, to a device for controlling the self-administered delivery of a fluid spray mist to the eye.

2. Prior Art

Eye treatment solutions are normally self-administered by using either an eye cup or a dropper. The rim of the eye cup is configured to fit snugly against the soft tissue surrounding the eye. Because of the eye cup rim's mating anatomical design, the rim forms a positive seal when placed over the eye and gently pressed against the infra-orbital tissue. In operation, a fluid such as an eye wash solution is placed in the eye cup and the cup is held against the infra-orbital tissue of the eye. The head is tilted back to allow the solution to immerse the eye. The head may also be moved from side to side to allow the solution to be fully distributed over the cornea and the peripheral tissues of the eye.

Another popular device for self-administering a fluid to the eye is a eye dropper. The eye drop solution is delivered directly into the eyes from either a dropper or a dropper type bottle. The person is usually lying down or has the head leaning back during administration. When using the dropper method of administration, one hand of the user pulls the lower lid away from the eye to expose the conjunctiva so that one or more drops of the solution can be introduced thereonto.

While most people can manage either the eye cup immersion or the eye drop method for the self-administration of a fluid to the eye, there is a segment of the population which find these devices and methods awkward or difficult to perform because of various visual and/or physical limitations. For example, individuals having partial or impaired vision, neuromuscular problems, muscular and/or skeletal disease, and those lacking hand/wrist coordination would fall into this group.

In addition to people having serious eye disorders requiring chronic delivery of medication, there are others suffering from eye irritation of a more temporary nature due to exposure to common irritants in both the home and the work place. The most common irritants such as dust and air laden chemicals, industrial particles, smoke, smog, pollen, and chlorinated water, all cause various degrees of eye irritation resulting in much discomfort to the individual. People troubled by dry eyes may also benefit from using an atomized eye wash solution for eye hydration. Such individuals require eye hydration on a frequent and chronic basis in order to attain a degree of eye comfort. In view of the foregoing, there is a need for a spray mist dispenser enabling the controlled and adjustable delivery of a fluid to the eye which is easy to self-administer, even for handicapped people, and does not require the user to assume a recumbent position to effect self-administration.

SUMMARY OF THE INVENTION

In view of the foregoing limitations of present devices for self-administering a fluid to the eye, it is a primary object of this invention to provide an eye solution mist dispenser device which is easy to use and acceptable to a wide range of users, even those with physical and visual limitations:

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It is another object of the invention to provide a device as above which is simple in construction and adapted to matingly and releasably attach to and engage the spray nozzle of prior art spray mist atomizers.

It is a further object of the invention to provide a device for controlling the distribution pattern of a fluid mist delivered to the surface of the eye.

It is yet another object of the invention to provide an eye spray mist device which delivers an adjustable and repeatable dose of medicament to the surface of the eye.

One or more of the following embodiments of the present invention satisfies the foregoing objectives. The device has a tube portion comprising concentric inner and outer robes. The inner tube (alternatively referred to as an "inner sleeve" herein), slides coaxially and telescopically within the outer tube (or alternatively, outer sleeve) and has one end adapted to matingly engage the (usually male) nozzle of a spray mist dispenser such as those currently employed for the nasal administration of drugs. Such prior art spray mist dispensers (for example, the 12H AFRIN® nasal spray pump, Schering Plough Health Care Products, Inc., Memphis, Tenn.) are manually operated by the user and designed to prevent aspiration of contaminated fluids or particles back into the dispenser's treatment solution reservoir. For example, if the spray dispenser's delivery nozzle is tapered, as is the case with most prior art spray mist dispenser nozzles, the interior wall of the end of the inner sleeve attaching to the nozzle (the dispenser end) is preferably tapered to matingly conform to and snugly receive the nozzle of the spray mist dispenser. At the dispenser end of the outer sleeve, two flexible tabs have a portion projecting inwardly are operable for locking engaging mating notches on the outer surface of the inner sleeve to set the length of the telescopically or slidably adjustable robe portion according to the degree of intensity of the eye spray mist required.

Providing the device with a tube portion having an adjustable length allows the device to function as a jig for adjusting and setting the distance between the spray mist dispenser's delivery nozzle and the rim of the eye cup portion. When the device is attached to a dispenser nozzle, extension of the tube portion moves the nozzle orifice further away from the eye cup portion and thus, when in use, the eye. Once the desired extension of the tube portion is reached, the tabs affixed thereto are locked in position by rotating the outer sleeve until the elastically flexible tabs engage a correspondingly spaced pair of mating notches on the inner sleeve. Readjustment of the length of the tube portion of the device is accomplished by rotating the outer tube either to the right or to the left until the tabs disengage from the notches on the inner tube, then sliding the outer tube to a new extension followed by a second rotation to engage the tabs with a new pair of notches. The device, when used in combination with a spray mist dispenser, enables the use of the spray mist dispenser to self-administer fluids such as eye wash solution to the eye. The compact size and ease of operation of the device makes it particularly useful for self-administration of fluids to the eye by individuals having physical and visual limitations.

The features of the present invention believed to be novel set forth with particularity in the appended claims. However, the invention itself, both as to organization and method of operation together with further objects and advantages thereof may be best understood by reference to the following description taken in conjunction with the accompanying drawings in which:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a preferred embodiment of the present invention.

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FIG. 2 is a partially cutaway side view of the embodiment of FIG. 1 showing the attachment of the device to a (prior art) aerosol dispenser.

FIG. 3 shows the device in accordance with FIG. 2 with the outer tube of the tube portion fully extended with respect to the inner tube.

FIG. 4 is a partially cutaway side view of an alternate embodiment of the device showing vent slots in the eye cup portion.

FIG. 5 is a vertical cross-sectional view of the embodiment of FIGS. 1 and 2 in accordance with the present invention showing the inner sleeve of the tube portion of the device attached to and matingly engaging the spray nozzle of a prior art dispenser.

FIG. 5A is an enlarged view of the tube portion showing a tab on the outer sleeve engaging a notch or detent rest on the inner sleeve.

FIG. 6 is a cross-sectional vertical view of the spray mist containment chamber.

FIG. 6a is a top view (in the direction of the broad arrow 6a in FIG. 6) showing the anatomically conforming shape of the delivery end of the chamber.

FIG. 7 is a bottom view of the spray mist chamber.

FIG. 8 is a vertical cross-sectional view of the outer sleeve of the tube portion showing the flexible tabs which engage the notches on the concentric inner sleeve of the tube portion of the device.

FIG. 9 is a vertical cross-sectional view of a portion of the outer tube showing the flexible detent tabs projecting inwardly when relaxed.

FIG. 10 is a perspective front view of the inner tube showing with the notches which function as detent rests for the tabs.

FIG. 11 is a cross-sectional view of the inner tube of FIG. 10, taken along section line 11—11 showing the flexible detent tabs engaging the detent rests.

FIG. 12 is an enlarged view of the boxed portion of FIG. 11.

FIG. 13 is an end view of the portion of the inner sleeve which matingly engages the nozzle of a prior art dispenser.

FIG. 14 is a side view of a notch or detent rest.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

A preferred embodiment of the device of the present invention is shown in FIG. 1. The device 10, which may alternately be referred to as a spray mist dispenser shield, is shown assembled and removably attached to the delivery tube or of a prior art hand pump type spray mist dispenser 12 (which may be alternatively referred to herein as an "atomizer", a "micromizer" or an "aerosol dispenser"), which dispenser may be releasably attached to a refillable fluid container 13. In FIG. 1, the tube portion of the device 10 is shown in its fully extended position. In operation the eye cup portion 11 of the device 10 is placed over the user's infra-orbital area 19 and is held in position with the thumb 17 of the person's right hand placed under the solution container 13 and with the first finger 16 and second finger 16 placed on the pump activator flange 14. When finger pressure is applied by the fingers to the pump activator flange 14, a spray mist is expelled through an escape orifice 22 in the nozzle or delivery tube 21, thereafter to pass through the inner and outer tube assembly 23 and through the eye cup 11.

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When the device is fully extended, this action provides for a fine spray mist treatment solution to be delivered to the eye.

A partial side view of a preferred embodiment of the present invention is shown in FIG. 2. The device 20 is shown in releasable mating engagement with the nozzle 21 of a (prior art) aerosol dispenser 12. The device 20 is shown with the tube portion in a retracted, unextended position. The device 20 is removably attached to the atomizer nozzle 21 by a friction fit between the nozzle 21 and the inner tube 24 of the device. Alternatively, an attachment means such as a detent rest or detent on the inner tube 24 can be employed to matingly engage a detent rest or detent on the nozzle 21 of a prior art dispenser as shown in FIG. 5 and 13. The eye cup portion 29 of the device is generally characterized as a hollow hemi-ellipsoid having an open elliptical end 27a having a skin-contacting rim 27b and a circular open end 27c opposite thereto. The eye cup portion 29 may be either removably attached to or permanently affixed to the outer tube 23 at the base 29 of the eye cup portion 11. The base 28 of the inner tube 24 is tapered on its inner surface to matingly conform to the tapered contour of the outer surface of the (prior art) dispenser nozzle 21. The mating engagement between the base 28 of the inner tube and the delivery nozzle 21 provides sufficient friction to prevent accidental disengagement of the device 20 from the nozzle 21. The skin-contacting rim 27b of the eye cup 29 is shaped to conform to the soft tissue surrounding the eye and to serve as a directional guide, as well as a seal, during delivery of a spray mist to the eye. The eye cup margin or rim 27b is preferably thicker than the wall of the eye cup 29 presenting a round, smooth, comfortable surface to the tissue surrounding the eye.

On the front surface of the eye cup 29 are two vent holes 26. These holes serve to relieve air pressure on the cornea of the eye which pressure may be created during the placement or removal of the device against the infra-orbital tissue. The spray containment chamber 25 is a (preferably molded) member shaped as the frustum of a cone and having means at the containment chamber's small diameter (distal) end for removable attachment to the interior of the eye cup 29 at its circular base. The purpose of the containment chamber 25 is to confine the delivery of the spray mist into a solid angle so that the mist may be delivered primarily to the cornea of the eye rather than to the general orbital area. The device 20 can be used to deliver fluid to the eye either with or without the spray mist chamber 25.

In FIG. 3, the end of the outer tube 23 to which the eye cup is attached is shown fully extended with respect to the base 28 of the inner tube. The inner tube 24 of the device 20 is removably seated on, and in mating engagement with, the (prior art) delivery nozzle 21. The interior cylindrical surface of the wall of the inner tube 24 is, as discussed earlier, tapered or otherwise shaped to conform to the exterior surface of the delivery nozzle 21 (prior art). The exterior surface of the inner tube 24 is cylindrical and dimensioned to slide within the outer tube 23. The maximum extension of the outer tube 23 is established by a travel limitation means such as a detent 31 on the outer surface of the inner tube 24 engaging a detent rest at 32 which may be a circular notch encircling the inner surface of the outer tube 23, to prevent further extension and disengagement of the inner and outer tubes.

An alternate embodiment of the device of FIGS. 2 and 3 is presented in FIG. 4 wherein vent slots 40 in the rim 27 of the eyecup 29 are used to prevent pressure from building within the eye cup in place of the vent holes 26 in the eye

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cup. The vent slots 40 are molded in the margin 27 of the eye cup and serve the same purpose as the vent holes 26.

A vertical cross-sectional view of a first embodiment of the device 10 of FIG. 2 which presents the main features representative of the present invention is shown in FIG. 5. In this embodiment 20, the inner tube 24 is shown mounted on a (prior art) atomizer nozzle 21. A portion of the outer surface of the inner tube 24 has a plurality of detent rests 51 arrayed thereupon. The detent rests 51 are preferably notches or similar indentations in the outer surface of the inner tube dimensioned to lockingly receive tabs 52 affixed to and projecting inward from the outer tube 23. The detent rests 51 and detent tabs 52 (shown in greater detail in FIGS. 5A, 8, 9 and 14), enable the intensity or dose of the spray mist delivered to the eye (or a portion thereof) to be reproducible by providing means for fixing the distance between the nozzle 21 and the rim 27 of the eye cup 20 for both comfort and accurate dosimetry. The outer tube 23 is shown fully extended and locked into position by flexible tabs 52, which are shown in greater detail in FIG. 8 and FIG. 9. In FIG. 5 and FIG. 5A, the base 28 of the inner tube 24 has a projection 28A extending upward to matingly engage a recess 28B (FIG. 9) in the base of the outer tube 23. This provides for the outer tube 23 to be properly positioned for extension, when required by the user. It also provides for the outer tube 23 to be properly positioned and locked in alignment for extension, when required by the user. It also provides for easier operation of the device by a user who has impaired vision or hand wrist coordination.

FIG. 5A is an enlarged view of the inner tube 24 showing the detent rests arrayed along the length of the outer surface of the inner tube. Detent rest 51, which receives the detent 52 (the flexible tab at the base end of the outer tube 23 shown in FIG. 9 at 52), serves four functions as shown in FIG. 14. The abrupt shoulder of the detent rest 51 prevents the accidental downward (collapsing) movement of the outer tube 23. The incline plane 51A portion of the detent 51 allows vertical movement when further extension of the device is required. The horizontal or lateral incline planes 51B and 51C provide means for the sliding, reversible disengagement of the flexible tab detents 52 from the detent rests 51 by the user by manually rotating the eye cup and the outer tube 23 relative to the inner tube. This rotation brings the flexible detent tabs 52 out of the notches and into contact with a portion of the inner tube having a smooth outer surface 100 (FIG. 11) so that the outer tube 23 can slide freely in relation to the inner tube 24. When the device is fully extended as shown in FIG. 5 and FIG. 5A, the detent 52 engages the upper most travel limiting detent rest on the inner tube 24. This terminal detent rest is different from the others inasmuch as it does not permit further extension there beyond. All other features of this detent rest are the same; including the release feature of the flexible detent tabs 52 from the detent rest by rotation of the eye cup which is affixed to the outer tube 23. As mentioned above, such a rotation causes the flexible detent tabs to ride up and out of the detent rest and brings the tabs into contact with the smooth outer surface 100 of the inner tube 24. In this position, the outer and the inner tubes may be moved telescopically for retraction or extension. section line 11—11 of FIG. 10 with the flexible detent tabs 52 seated in the detent rests. FIG. 12 provides a cross-sectional view of the inner tube 24 and the outer tube 23 with the flexible detent tab 52 engaging a detent rest at 111. The spaces 110 at the right and the left of the flexible detent tab 52 and the lateral incline spaces 51B and 51C as shown in FIG. 14 permits the fine adjustment of the eye cup either to the right

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or to the left when it is brought into contact to the orbital area. This adjustment feature is important in order to accommodate those users who might have a problem with the hand wrist coordination or some other physical limitation.

FIG. 8 shows the flexible detent tab 52 at the nozzle end of the outer tube. FIG. 9 shows a sagittal of the flexible detent tabs 52 on the outer tube in an unstressed condition: that is, as they appear when the inner tube wall is not pressing on the detent tab, showing a slight deflection inwardly so that the internal ridges of the flexible detent tabs 52 will engage and seat within the detent rest, as the tabs slide along the outer surface of the inner tube 24.

FIG. 13 shows cross section of the inner tube 24, at its base areas and detents at 112 to secure the inner tube in place to the base of the delivery tube 21, detent rest not shown (prior art).

Returning now to FIG. 6 which is a cross-sectional view of the spray mist chamber 25, a further embodiment is shown. FIG. 6A shows an embodiment of the containment chambers having an elliptical eye-facing open end to conform to orbital area 19. FIG. 7 shows the base of the spray mist chamber 63 to be cylindrical in shape. In FIG. 6, the wall 61 of the spray mist chamber is seen to diverge, the open end 64 terminating into either an elliptical shape as shown in FIG. 6A or a circular shape. Changing the shape of the containment chamber creates a greater or smaller internal space 65 for confining the spray mist as it fans out before it reaches the eye area.

The tube portion of the device can be telescopically retracted to its most compact position, placing the spray nozzle at the nearest position to the eye. When the tube portion is completely retracted, the outer tube is rotated until an indentation on the nozzle end of the outer tube engages an indexing tab projecting from the base of the inner tube. This locating and locking device serves to position the outer tube in alignment so that when extension of the tube position is required, the flexible detent tabs 52 will be in the correct position to engage the notches or similar detent rests on the outer surface of the inner tube. This automatically places the assembly in alignment for extension.

The device is preferably sterilizable and compact for portability. The eye wash solution reservoir, if the device is permanently affixed to and an integral part of, a fluid mist dispenser is preferably small and refillable. The portable, compact unit is ideal for users who require frequent eye hydration, for home use, a larger version utilizing the same basic principles of design of the smaller portable unit but having a larger eye wash reservoir may be preferable.

Cleanliness of the eye spray mist dispenser device is of the utmost importance to prevent introducing foreign matter such as dust particles, and other debris into the eye. The most important concern is preventing any pathogens, including fungi, yeast, bacteria and viruses from contaminating the solution and/or the mist contacting surfaces of the device which could cause an infection of the eye. The user should take certain precautions to keep the eye spray mist dispenser device clean and free from contaminated material. Care should be exercised to prevent the fingers from touching the orifice of the dispenser nozzle. Rinsing the device with water before and after use is recommended. At intervals, a more complete maintenance should be done by a disassembly of the component parts so each could be cleaned separately. The device is preferably stored in a dust proof container.

There is a large segment of the population that suffers from dry eye syndrome and require frequent eye hydration. Such individuals require treatment a number times a day to

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attain an acceptable degree of eye comfort and the device described herein above is particularly useful for such people.

While particular embodiments of the present invention have been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the invention. It is therefore intended to cover in the appended claims all such changes and modifications which are within the scope of this invention.

What we claim is:

1. A device operable for controlling the delivery of a fluid mist discharged from the ejection nozzle of a spray mist dispenser to a person's eye comprising:

(a) a hollow hemi-ellipsoidal eye cup having a substantially elliptical proximal open end dimensioned to encircle a person's eye and having a skin-contacting rim on said open end contoured to anatomically conform to infra-orbital tissue adjacent to the person's eye and a distal circular open end;

(b) an axially adjustable tube portion comprising a cylindrical outer tube concentrically overlying a cylindrical inner tube, and having an axial mist-conducting lumen coextensive therewith, said outer tube having a proximal end attached to said eye cup to provide fluid communication between said mist-conducting lumen and said distal circular open end of said eye cup and a

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distal end, said inner tube being slideably disposed within said outer tube and having a proximal end and a distal end, said distal end of said inner tube including attachment means adapted to releasably attach to the nozzle of the spray mist dispenser, said mist-conducting lumen providing a conduit having an adjustable axial length operable for conducting a fluid mist from said distal end of said inner tube to said proximal end of said outer tube.

2. The device of claim 1, wherein said proximal end of said outer tube of said tube portion is rigidly affixed to said circular open end of said eye cup.

3. The device of claim 1 wherein said tube portion further comprises locking means operable for releasably locking said telescopically adjustable tube portion at a preferred length.

4. The device of claim 1 wherein said eye cup further includes a flow channel operable for conducting gas therethrough releasing excessive pressure within the eye cup when said proximal end and said distal end of said eye cup are occluded.

5. The device of claim 2 wherein said eye cup further includes means operable for maintaining ambient pressure within the eye cup when said proximal end and said distal end of said eye cup are occluded.

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